EFFECTS OF ALCOHOL CONSUMPTION DURING PREGNANCY

HEARING

BEFORE THE

SUBCOMMITTEE ON
ALCOHOLISM AND DRUG ABUSE

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

TO EXAMINE THE EFFECTS OF MATERNAL ALCOHOL CONSUMPTION DURING PREGNANCY

SEPTEMBER 21, 1982

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EFFECTS OF ALCOHOL CONSUMPTION DURING PREGNANCY

TUESDAY, SEPTEMBER 21, 1982

U.S. SENATE,
SUBCOMMITTEE ON ALCOHOLISM AND DRUG ABUSE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 11:30 a.m., in room 1202, Dirksen Senate Office Building, Senator Gordon J. Humphrey (chairman of the subcommittee) presiding.

Present: Senator Humphrey.

OPENING STATEMENT OF SENATOR HUMPHREY

Senator HUMPHREY. Will the hearing come to order, please?

Today, the Alcoholism and Drug Abuse Subcommittee is meeting to explore an area in which modern research has provided us the opportunity to prevent a major cause of birth defects. I hope that today's hearing on fetal alcohol effects will clarify the results of recent research so a clear message can be sent to women on the specific nature of the risks of alcohol consumption during pregnancy. In addition, it is important that the subcommittee explore approaches which have been used and those which are planned to raise public awareness on this important issue.

In a recent speech, Richard Schweiker, Secretary of Health and Human Services, indicated that a major focus of this administration will be prevention; that is the utilization of information we have gathered through research to foster the health habits which will prevent disease.

The effect of alcohol on the fetus is an area where Secretary Schweiker's efforts have the potential for producing positive and swift results. Indeed, in the broader field of alcohol and drug abuse, prevention is one of the most promising approaches to curbing the enormous damage caused human lives every year by alcohol and drug abuse, and I wholeheartedly endorse this effort by Secretary Schweiker.

Although incidence data for the United States are limited, data from other countries suggest that fetal alcohol syndrome may be among the top three leading causes of birth defects with mental impairment. The Fourth Special Report to the U.S. Congress on Alcohol and Health issued in January 1981 indicated that when incidence data were evaluated in two European cities, an incidence of 1 in 600 births was diagnosed as definite fetal alcohol syndrome, with an equal number of probable fetal alcohol syndrome cases.

This incidence, the report noted, is greater than the incidence of the two currently considered most common birth defects associated with a significant incidence of mental impairment in the United States.

I understand that the Center for Disease Control is beginning to collect incidence data in this country, and our witnesses today will shed some light on this issue. Application of this data to our society provides us with both a valuable opportunity to prevent a leading cause of birth defects and a grave responsibility. We must meet that challenge by insuring that mothers to be are made aware of the potential risks of alcohol consumption during pregnancy.

The purpose of today's hearing is to explore both the current state of the art in research and the efforts of Government, private industry, and the voluntary sector in disseminating this critical information. I feel strongly that our medical research efforts are critical, but they must be coupled with aggressive information dissemination in order to reap their benefits and exert the maximum impact on our lives.

We are fortunate to have with us this morning Dr. Edward Brandt, Assistant Secretary for Health at the Department of Health and Human Services. Dr. Brandt was Acting Surgeon General when the advisory on alcohol and pregnancy was issued, and has been active in the Department's efforts to disseminate information on this important health issue.

In addition, we have as witnesses leading researchers and clinicians in fetal alcohol effects, who will bring us up to date on the impact of alcohol consumption during pregnancy. They will be joined by representatives of the American Medical Association and the American College of Obstetricians and Gynecologists.

The members of these organizations, of course, are the practitioners who play such a vital role in keeping patients informed of the latest medical findings. Indeed, the subcommittee hopes to hear from these representatives about how doctors are being kept abreast of the most recent information through both updating of medical school curricula and ongoing medical education.

Finally, and of critical importance, represented here today are the Licensed Beverage Information Council, the National Council on Alcoholism, and the March of Dimes. These groups represent private industry and the voluntary sector, all of whom have worked diligently to see that women hear the message on the risks of alcohol consumption during pregnancy. Public information campaigns sponsored by each of these organizations, as well as the Federal Government, have played an important part in insuring public awareness of the problem.

In closing, let me express my hope that today's hearing will present a clear picture of the nature of the effects of maternal alcohol use and abuse during pregnancy, and provide for us an understanding of the measures needed to achieve a more complete public awareness of the risks involved.

Before we go to our witnesses, let me thank everyone for their cooperation in adjusting to the changed time for this hearing. It was unavoidable. I had an appointment with the President this morning that came up after the hearing was scheduled.

I hope everyone has enough room in this particular hearing room. I hope you are not too crowded. Again, because we had to switch times, we had to change rooms.

At this time we will receive for the record a prepared statement from Senator Hatch, chairman of the full committee.

[The following was received for the record:]

PREPARED STATEMENT OF SENATOR HATCH

Senator **HATCH**. Mr. Chairman, the problems of alcohol consumption during pregnancy are extremely serious. Misuse and abuse of alcohol affects everyone—and it is completely preventable. Not only do birth defects affect the victim, but parents, siblings and society at large is adversely affected, I am committed to the well-being of our Nation's children, and am pleased that this issue is receiving the attention of this committee.

In July 1981, the Surgeon General issued an advisory on alcohol and pregnancy. This advisory spotlighted research showing that alcohol can cause birth defects in humans. The Surgeon General advises women who are pregnant, or considering pregnancy, not to drink alcohol at all. Alcohol and pregnancy do not mix.

During pregnancy, the fetus is completely dependent on the mother to provide the nutrients for physical development. Alcohol in the mother's blood passes directly through the placenta into the baby's blood stream, and can adversely affect fetal development. During the first trimester, vital organs and other body parts are formed. Growth of the body and brain continue throughout pregnancy, and the building blocks for this growth continue to be taken from the mother's blood stream through the placenta. When the well-being of a child is so important, expectant mothers who drink are placing a health risk on their child's life. In a report to the Governor of New York, a task force on fetal alcohol syndrome estimated that in New York State alone 386 babies were born with fetal alcohol syndrome, and approximately 1,563 more babies were born with alcohol-related birth defects in 1978. The lifetime costs of caring for babies born in New York State with FAS/ARBD in a single year were estimated at almost $155 million. Today Dr. Edward Brandt, Assistant Secretary for Health at the Department of Health and Human Services will testify that a "conservative estimate of severe and irreversible abnormalities (caused by FAS) is estimated at 1,800 to 2,400 births a year and an estimated 36,000 pregnancies will be affected by other adverse alcohol-related problems." The costs are staggering, estimated at over $1.5 billion a year. But in no way can we measure the emotional drain this costs our society.

I look forward to the testimony received today. It is time for the Congress to bring this issue into the forefront. We must continue the efforts to warn people about this preventable problem.

Senator **HUMPHREY**. Our first panel, as I have earlier noted, is comprised of Dr. Edward Brandt, Jr., Assistant Secretary for Health, and he is accompanied this morning by Dr. William Mayer, who is the distinguished Administrator of the Alcohol, Drug Abuse and Mental Health Administration.

Good morning, gentlemen. Dr. Brandt, will you proceed with your testimony? Let me state one more caveat here. I have to leave here at 2:45 for a meeting with Secretary Lewis downtown, and so we will have to be economical with our time this morning, if I may have your cooperation on that point.

STATEMENT OF EDWARD N. BRANDT, JR., ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY WILLIAM MAYER, ADMINISTRATOR, ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

Dr. **Brandt**. All right, sir. Mr. Chairman, as you noted, I am accompanied by Dr. William Mayer, who is the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, which is the agency that has the primary responsibility for our research and educational efforts within the Public Health Service.

We are pleased to be here today to have the opportunity to share with you our deep concern about the risks of alcohol consumption during pregnancy and the efforts that we are making to inform the public, particularly prospective parents and health care providers, about these risks.

Alcohol consumption during pregnancy poses a significant risk for the unborn child, with consequences including increased spontaneous abortion, decreased birth weight, major and minor birth defects, and mental retardation.

Some of these effects occur in children whose mothers during pregnancy consumed alcohol in amounts consistent with a diagnosis of alcoholism. Some occur in children whose mothers drink moderately. But I want to make it very clear that we are not describing rare or isolated events. In the United States, the incidence of fetal alcohol syndrome—a specific cluster of severe and irreversible abnormalities—is conservatively estimated at 1,800 to 2,400 births a year. The incidence of a broad range of other adverse alcohol-related outcomes is as much as 20 times as high, affecting an estimated 36,000 pregnancies each year. To put that in proper perspective, Mr. Chairman, that is equal to approximately one out of every 100 live births in the United States, and all of it is completely preventable.

Now, I would like to describe these problems for you in somewhat more detail. At the extreme end of the continuum of risk are children born with the specific cluster of abnormalities which has been named the fetal alcohol syndrome. Its most consistent features are mental impairment, small head circumference, pre- and post-natal growth deficiencies, irregularities of the head and face, and defects of such organs as the heart and of the renal, genital, and skeletal systems.

The incidence of fetal alcohol syndrome in the United States is conservatively estimated at between 1 per 1,500 to 2,000 live births. It appears clear that the incidence of fetal alcohol syndrome in the United States is similar in magnitude to the incidence of Down's syndrome and spina bifida. Together, these constitute the leading known causes of birth defects with mental impairment. Of these three, fetal alcohol syndrome is uniquely preventable.

Alcohol consumption during pregnancy also increases the risk of complications during pregnancy and a broad range of other adverse effects on the fetus. The possibilities of any of these adverse occurrences is as much as 20 times the incidence of fetal alcohol syndrome.

In a large, prospective study, problems found, which were independent of smoking, included infection of the amniotic fluid, premature separation of the placenta, uterine tetany, precipitous delivery, small-for-gestation-age weight, low Apgar score, congenital abnormalities, and histories of habitual spontaneous abortions.

These problems which occur as a consequence of alcohol misuse in pregnancy are apart from the fetal alcohol syndrome, and they have been termed fetal alcohol effects or alcohol-related birth defects. Some of these occur even at moderate levels of alcohol consumption.

For example, women who average 1 ounce of absolute alcohol—that is, two drinks per day—in the period immediately prior to pregnancy deliver children who are an average 91 grams lighter than occasional drinkers and abstainers. Women who report drinking at the level of one to two drinks per day are at twofold higher risk for spontaneous abortions than women who are abstinent or occasional drinkers.

A prospective study of the children of women who drink at moderate levels during pregnancy—that is, one ounce or more of absolute alcohol per day—provides the following interesting findings: At birth, decrements in neurological and behavioral attributes; at 8 months of age, small but significant lags in mental and motor development; and morphology consistent with some attributes of the fetal alcohol syndrome.

Consumption of one standard drink has been shown to significantly suppress fetal breathing movements, indicating a physiological even at this low dose on the fetal central nervous system.

Alcohol may also have residual effects on women who were alcoholic but who abstained during pregnancy.

Senator **HUMPHREY**. Doctor, pardon my interruption, but it seems opportune to question you on this point.

Dr. **BRANDT**. Yes.

Senator **HUMPHREY**. You say that as little as one drink has been shown to have the effect of suppressing respiration.

Dr. **BRANDT**. In the fetus, yes; that is correct.

Senator **HUMPHREY**. Does that mean that alcohol or some byproduct of it passes almost immediately through the placenta?

Dr. **BRANDT**. It would appear that alcohol or some byproduct of it must pass through the placenta, although the exact mechanism of the effect on the placenta of alcohol consumption is really not well worked out. It seems reasonable. It was from these kinds of data that I found it prudent to say that it is not possible for us to define a safe level of drinking for women who are pregnant, and therefore to advise women who are pregnant not to drink at all.

Senator **HUMPHREY**. Are you saying then that when a mother drinks, she is actually serving a drink to her unborn child? Is that a fair statement?

Dr. **Brandt**. Well, she is at least serving something to her unborn child, and the evidence thus far is that that something is not helpful, and certainly is probably harmful.

Senator **Humphrey**. And even just one drink has been shown to have that effect?

Dr. **Brandt**. That is correct.

Senator **Humphrey**. So that the perception is that fetal alcohol syndrome or any of the effects associated with drinking while pregnant are not limited to heavy drinkers but even to those who consider themselves just occasional or social drinkers, is that correct?

Dr. **Brandt**. That is correct.

Senator **Humphrey**. Thank you. I thought it would be good to clarify that, and I apologize for interrupting you.

Dr. **Brandt**. That is fine.

We have a number of questions that have been raised regarding consequences of long-term alcohol abuse and of long-range effects of alcohol abuse on the female reproductive system. Furthermore, it does seem clear that women who abuse alcohol before conception and/or even during pregnancy can decrease the risks to their fetuses by abstaining throughout the remainder of pregnancy.

Thus, at this time it is clear that women who abuse alcohol during pregnancy place themselves and their offspring at a substantial risk for a wide range of adverse perinatal and neo-natal occurrences and outcomes.

Moderate drinking—that is, alcohol consumption at the level of two drinks per day—is associated with decreased birth weight and behavioral deficits. Furthermore, increased spontaneous abortions have been observed for women who report drinking one to two drinks per day.

As I said a moment ago, there is as yet no known safe level of alcohol consumption during pregnancy. I want to emphasize two points, Mr. Chairman. The deformities, retardation, learning disabilities and other lesser manifestations of alcohol consumption on our offspring can be prevented. Two, the effects on pregnancy of alcohol consumption are independent of other potentially confounding variables, including nutrition, smoking, caffeine and use of other drugs.

Evidence from animal studies has helped to isolate alcohol as the teratogenic agent. The large number and variety of animal species which have been shown to exhibit alcohol-derived teratogenic effects confirms the results obtained in human studies.

The Federal response to the knowledge we have gained over the last decade on the effects of alcohol consumption during pregnancy has consisted of: One, continued support of research; two, vigorous public education; and, three, heightened professional education.

Since 1972, the National Institute on Alcohol Abuse and Alcoholism has awarded nearly $8 million for human and animal studies on the effects of alcohol on the fetus. At present, the Institute is supporting 10 fetal alcohol research projects totaling $1.1 million. Of this, $218,000 is being used for prospective studies of the development of children born to mothers who drink during pregnancy.

There have been a number of results found from this research and they are outlined in my full testimony. In the interest of time, I will not go through those, however.

As you know, Mr. Chairman, the President requested a 57-percent increase in fiscal year 1983 for research carried out by the National Institute on Alcohol Abuse and Alcoholism. If appropriated, some of these funds would be used to explore such questions as the effects of binge drinking and the average effective threshold dose of alcohol for teratogenesis; the mechanisms underlying adverse effects of alcohol on offspring; the effects of perinatal alcohol exposure on the long-range development of children of mothers who drink moderately; the long-range development of children without the fetal alcohol syndrome but who are born to alcoholic mothers; and the development and validation of a questionnaire to provide greater reliability and accuracy in obtaining information on alcoholic beverage consumption.

Our major public education initiatives include: a media campaign designed to educate the public about alcohol problems among women and youth; and ongoing informational services provided through NIAAA's National Clearinghouse for Alcohol Information.

With your permission, I would like to insert in the record a list of the major activities we have taken to inform individuals of the risks of drinking during pregnancy, and briefly summarize a few of these activities now. And I should say, Mr. Chairman, that we have brought some of our publications and put them on the table over here, and have one of our posters. We will also have some video spots in a few moments.

Senator **HUMPHREY**. Fine.

Dr. **BRANDT**. One of these is a public education brochure called "Alcohol and Your Unborn Baby." Approximately 5 million copies of that brochure have been distributed. NIAAA, through its clearinghouse, collaborated with the Bureau of Alcohol, Tobacco and Firearms in distributing a 30-second TV public service announcement on alcohol consumption during pregnancy.

We also have produced an illustrated booklet about fetal alcohol syndrome, and over 400,000 copies of that has been distributed in English and 100,000 copies in Spanish. We are also engaged in vigorous efforts to keep health care professionals abreast of the most recent knowledge regarding alcohol consumption during pregnancy. In July 1981, as Acting Surgeon General, I issued a formal advisory on the risks of alcohol consumption during pregnancy. That advisory was published in the FDA drug bulletin which is distributed to almost 1 million physicians, medical students, dentists, and pharmacists.

In August 1981, an article summarizing scientific knowledge concerning health hazards associated with alcohol consumption was printed in the Journal of the American Medical Association. This article was written by NIAAA staff.

Our National Clearinghouse for Alcohol Information developed a package of fetal alcohol syndrome and effects, with technical information for health care providers. A booklet for medical practitioners, called "Preventing Fetal Alcohol Effects: A Practical Guide for OB/GYN Physicians and Nurses," became available in April 1982.

So, there have been a number of these. This latest one, "Preventing Fetal Alcohol Effects," several organizations have agreed to promote, and that includes the American Academy of Physicians' Assistants, the Association of American Indian Physicians, the

American Indian/Alaskan Native Nurses Association, and so on and so forth, to include a large number of organizations who are distributing it to their membership.

A new research-oriented booklet on fetal alcohol facts for caregivers is currently under development, as well as curriculum guides and lists of resources for use in the professional and continuing education of health profession educators.

In summary, Mr. Chairman, we know some of the effects and risks of alcohol consumption during pregnancy. We also know that the risks can be eliminated. The effects can be prevented. Because a safe level of alcohol intake has not been established for the pregnant woman, we advise women who are pregnant or considering pregnancy not to drink alcoholic beverages.

[The prepared statement of Dr. Brandt follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

FOR RELEASE ONLY UPON DELIVERY

STATEMENT BY

EDWARD N. BRANDT, JR., M.D.

ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

ALCOHOL CONSUMPTION DURING PREGNANCY

BEFORE THE

SENATE SUBCOMMITTEE ON ALCOHOLISM

AND DRUG ABUSE

SENATE COMMITTEE ON LABOR AND

HUMAN RESOURCES

SEPTEMBER 21, 1982

Mr. Chairman and Members of the Subcommittee:

We are pleased to have the opportunity to be here today to share with you our deep concern about the risks of alcohol consumption during pregnancy and the efforts we are making to inform the public, particularly prospective parents and health care providers, about these risks.

Over the last decade, there have been many studies of the effects of alcohol consumption during pregnancy. These studies have been conducted in both animal and human populations, both prospectively and retrospectively -- and their findings are clear and compelling. Alcohol consumption during pregnancy poses a significant risk for the unborn child -- with consequences including increased spontaneous abortion, decreased birth weight, major and minor birth defects, and mental retardation.

Some of these effects occur in children whose mothers, during pregnancy, consumed alcohol in amounts consistent with a diagnosis of alcoholism. Some occur in children whose mothers drank moderately. But I want to make it very clear that we are not describing rare or isolated events. In the United States, the incidence of the fetal alcohol syndrome -- a specific cluster of severe and irreversible abnormalities -- is conservatively estimated at 1,800 to 2,400 births a year. The incidence of a broad range of other adverse alcohol-related outcomes is as much as 20 times as high, affecting an estimated 36,000 pregnancies each year. And all of it is completely preventable.

I would like now to describe these problems for you in more detail.

FETAL ALCOHOL SYNDROME

At the extreme end of the continuum of risk are children born with the specific cluster of abnormalities which has been named the fetal alcohol syndrome (FAS). Its most consistent features are: mental impairment, small head circumference, pre- and post-natal growth deficiency, irregularities of the head and face, and defects of such organs as the heart and of the renal, genital and skeletal systems. Not all of these abnormalities appear in every affected child. Nor is every child born of an alcoholic woman affected. But the defects that do occur are attributable to alcohol.

As I noted earlier, the incidence of the fetal alcohol syndrome in the U.S. is conservatively estimated at between 1 per 1,500 to 2,000 births or 1,800 to 2,400 children per year. In two European cities (Roubaix, France and Goteborg, Sweden) where organized studies could be undertaken to more accurately assess the occurrence of the syndrome, incidences between 1 per 600 to 1,000 births were observed. It appears clear that the incidence of FAS in the U.S. is similar in magnitude to the incidence of Down's syndrome and spina bifida; together, these constitute the leading known causes of birth defects with mental impairment. Of these, FAS is uniquely preventable.

OTHER EFFECTS OF ALCOHOL CONSUMPTION DURING PREGNANCY

Alcohol consumption during pregnancy also increases the risk of complications during pregnancy and a broad range of other adverse affects on the fetus. The possibilities of any of these adverse occurrences is as much as 20 times the incidence of FAS.

In a large prospective study on alcohol and pregnancy at Cleveland's Metropolitan General Hospital, while 2.5% of the women defined as alcohol abusers delivered children diagnosed with the FAS, fully 50% of the pregnancies had maternal and/or neo-natal complications, even with confounding from smoking and other factors controlled. Problems which were independent of smoking included infection of the amniotic fluid, premature separation of the placenta, uterine tetany, precipitous delivery, small-for-gestation-age weight, low Apgar score (a quantitative rating of a newborn's condition), congenital abnormalities, and histories of habitual spontaneous abortions.

These neonatal and maternal problems which occur as a consequence of alcohol misuse in pregnancy and are apart from the fetal alcohol syndrome have been termed Fetal Alcohol Effects (FAE) or Alcohol-Related Birth Defects (ARBD). Some of these occur even at moderate levels of alcohol consumption. Research has provided some information on this subject, as well. For example:

- Women who average one ounce of absolute alcohol (two drinks) per day in the pre-pregnancy period deliver children who are an average 91 grams lighter than occasional drinkers and abstainers. With this level of alcohol consumption in late pregnancy, the weight decrement is 160 grams. Decreases in birth weight are typically associated with an increase in the percentage of small-for-gestation age infants; increased neo-natal risk is well established for infants who are small-for-gestation-age.
- Women who report drinking at the level of one to two drinks per day are at two-fold higher risk for spontaneous abortions than women who are abstinent or occasional drinkers.

- A prospective study of the children of women who drank at moderate, social levels during pregnancy — one ounce (two standard drinks) or more of absolute alcohol per day before or during pregnancy — provides the following statistically significant findings:
  - at birth, decrements in neurological and behavioral attributes such as increased time spent with open eyes, increased body tremor, atypical head orientation, decreased levels of body activity, and large increased self-stimulatory behavior;
  - at 8 months of age, small but significant lags in mental and motor development; and
  - morphology consistent with some attributes of the fetal alcohol syndrome.
- Consumption of one-half ounce of absolute alcohol (one standard drink) has been shown to significantly suppress fetal breathing movements, indicating physiological action of alcohol, even at this low dose, on the fetal central nervous system. While the pathologic significance of this effect is unknown, it does suggest cause for caution and further research.
- Alcohol may have residual effects on women who were alcoholic but who abstain throughout pregnancy. One preliminary study has shown that children born to abstinent recovering alcoholic mothers, when abstinent less than one year, have significant decrements in intellectual developments when compared to (well-matched control) children born to nonalcoholic mothers. This raises questions regarding consequences of long-term alcohol abuse and long-range effects on the female reproductive system.

- Women who abuse alcohol before conception and/or during pregnancy can decrease, if not eliminate, the risks to their fetuses by abstaining throughout the remainder of pregnancy.

SUMMARY OF RESEARCH FINDINGS

Thus, at this time, it is clear that women who abuse alcohol during pregnancy place themselves and their offspring at a substantial risk for a wide range of adverse perinatal and neo-natal occurrences and outcomes. Moderate drinking -- for example, alcohol consumption at the level of two drinks per day -- is associated with decreased birth weight and behavioral deficits. Increased spontaneous abortions have also been observed for women who report drinking one to two drinks per day. There is as yet no known safe level of alcohol consumption during pregnancy And, decreases in birth weight appear to be associated with alcohol consumption averaging two drinks per day prior to pregnancy.

I want to emphasize two points, Mr. Chairman: (1) the deformities, retardation, learning disabilities, and other lesser manifestations of alcohol consumption on our offspring can be prevented, and (2) the effects on pregnancy of alcohol consumption are independent of other potentially confounding variables including nutrition, smoking, caffeine, and other drug use.

Evidence from animal studies has helped to isolate alcohol as the teratogenic agent. The large number and variety of animal species which have been shown to exhibit alcohol-derived teratogenic effects confirms the results obtained in human studies.

FEDERAL RESPONSE

Our responce to the knowledge we have gained over the last decade on the effects of alcohol consumption during pregnancy has consisted of (1) continued support of research, (2) vigorous public education, and (3) heightened professional education.

Promising Ongoing Research Activities

Since 1972, the National Institute on Alcohol Abuse and Alcoholism has awarded nearly $8 million for human and animal studies on the effects of alcohol on the fetus.

At present, the Institute is supporting ten fetal alcohol research projects totaling $1.1 million. Of this, $218,000 is being used for prospective studies of the development of children born to mothers who drink during pregnancy.

The remainder of current Institute funding in fetal alcohol research involves projects using animal models ($926,000). To date, these ongoing efforts have furnished us with a number of observations appropriate for further inquiry -- among them:

- Both male and female drinking histories prior to conception and/or during pregnancy may play a role, from a teratological perspective, in fetal growth and development. In one animal study assessing the female parent using sophisticated techniques involving ova transfer, we hope to separate alcohol-induced genetic damage prior to pregnancy from in utero alcohol damage to the developing fetus.
- Thyroid hormones appear to play an important role in fetal growth and development. Alcohol exposure in utero appears to depress

fetal pituitary-thyroid function and increase fetal adrenal function. At this point, we do not know whether alcohol-induced endocrine imbalance contributes to the cause of the fetal alcohol syndrome; however, it is possible that fetal endocrine function and intrauterine growth are related.

- Alcohol exposure during the third trimester appears to cause greater deficits in both weight and body length than exposure during the first and second trimesters.
- *In utero* exposure to alcohol at abusive levels appears to produce an enduring and irreversible reduction in the number of prenatally formed neurons in certain regions of the brain. The damage caused is dose-related; the changes are still observed 60 days after birth in experimental rats.
- Alcohol impairs placental transport of amino acids and possibly other nutrients -- thereby reducing the nutrients absorbed by fetal tissue and possibly altering fetal growth.
- Evidence now points to alcohol as a behavioral teratogen in humans. Fetal alcohol syndrome children and rats exposed to alcohol prenatally display behavioral dysfunctions such as attention span deficits, problems with feeding, and hyperactivity. In addition, we continue to explore the types and management of behavioral abnormalities that occur at alcohol levels that do not produce gross physical anomalies.

Our intramural scientists have recently developed a new technique for identifying individuals with drinking problems. They are now working in cooperation with the National Naval Medical Center to test the applicability of this technique to women and, in particular, to women who are pregnant.

The technique relies upon a sophisticated analysis of blood chemistries that are obtained routinely as part of a general physical examination. If the technique proves successful with pregnant women, a physician would have an objective indicator of when a pregnant woman might be drinking at a level which increases the risk of having a child with an alcohol-related birth anomaly or defect.

In addition, several of the National Alcohol Research Centers continue to conduct research in areas of relevance to alcohol-related birth defects. NIAAA has also sponsored two research workshops on the fetal alcohol syndrome and alcohol-related birth defects. The proceedings of the most recent workshop, held in May 1980, were published in the Summer 1981 issue of the Journal of Neurobehavioral Toxicology and Teratology.

The National Institute of Health's Institute of Child Health and Human Development, as part of its research on a range of aspects affecting development, is examining the effects on the infant of alcohol received through lactation. In addition, the Institute plans to continue its support of ongoing research on the effects of alcohol ingested during pregnancy on the offspring's behavioral development in infancy and early childhood.

As you know, Mr. Chairman, the President requested a 57% increase in FY 1983 for research carried out by the National Institute on Alcohol Abuse and Alcoholism. If appropriated, some of these funds would be used to explore such questions as:

- the effects of binge drinking and the average effective threshold dose of alcohol for teratogenesis,
- the mechanisms underlying adverse effects of alcohol on offspring,

- the effects of perinatal alcohol exposure on the long-range development of children of mothers who drink moderately,
- the long-range development of children without the fetal alcohol syndrome born to alcoholic mothers, and
- the development and validation of a questionnaire to provide greater reliability and accuracy in obtaining information on alcoholic beverage consumption.

Public Education

Our major public education initiatives include (1) a media campaign designed to educate the public about alcohol problems among women and youth, and (2) ongoing informational services provided through NIAAA's National Clearinghouse for Alcohol Information.

In July 1980, the National Institute on Alcohol Abuse and Alcoholism awarded a contract for (1) the development of television, radio, and print materials on the fetal alcohol syndrome and alcohol-related birth defects, alcohol problems among women, and alcohol problems among youth, and (2) assistance in implementing this campaign. As a result of this campaign, still in progress, States are also developing their own materials, conducting training programs, and initiating a number of other public education and prevention activities.

The present media campaign represents our latest effort to raise the awareness of American women about the risks of drinking during pregnancy -- an effort that reaches back to 1977. With your permission, I would like to insert in the record at this point, a list of the major activities we have taken to inform individuals of the risks of drinking during pregnancy and briefly describe just a few of these activities now.

- NIAAA's Clearinghouse developed a public education brochure and poster called Alcohol and Your Unborn Baby. Approximately 5 million copies of the brochure and 2 million posters have been distributed; last year, nearly 88,000 copies of the brochure were requested. Special mailings have been made to obstetricians/gynecologists, family physicians, and over 8,000 health care agencies. The American College of Obstetricians and Gynecologists is currently reprinting Alcohol and Your Unborn Baby at its own expense as part of its Patient Information Series.
- NIAAA, through its Clearinghouse, collaborated with the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms (BATF) in distributing a 30-second TV public service announcement on alcohol consumption during pregnancy.
- The second product cf the NIAAA collaborative effort with the BATF was an illustrated booklet about the fetal alcohol syndrome, based on characters from the Rex Morgan, M.D. comic strip. Three versions of this comic book were produced and distributed: 400,000 copies in English; 100,000 in Spanish; and 10,000 copies for Native Americans.
- We find that many segments of the American public — such as women's groups, health clinics, and State and community agencies — are interested in carrying out information and prevention programs on fetal alcohol effects. To assist these groups, NIAAA's Clearinghouse has developed a new 16-page guide on available print and audiovisual materials. It is titled A Selective, Annotated Resource Guide on Fetal Alcohol Effects.

Professional education

We are also engaged in vigorous efforts to keep health care professionals abreast of the most recent knowledge regarding alcohol consumption during pregnancy. We approach health care professionals in a variety of ways -- among them, basic professional education, continuing education, professional journals, professional associations, and direct communication.

- In July 1981, as Acting Surgeon General, I issued a formal Advisory on the risks of alcohol consumption during pregnancy. The Advisory summarized scientific knowledge about these risks and urged physicians and other health professionals to advise patients who are pregnant or considering pregnancy not to drink alcoholic beverages. The Advisory was published as the lead article in the FDA Drug Bulletin, which is distributed to almost 1 million physicians, medical students, dentists, and pharmacists.
- In August 1981, an article summarizing scientific knowledge concerning health hazards associated with alcohol consumption was printed in the Journal of the American Medical Association. This article, written by NIAAA staff, included a section on the hazards of alcohol consumption during pregnancy.
- In 1980, NIAAA's National Clearinghouse for Alcohol Information developed a package of fetal alcohol syndrome and effects technical information for health care providers, including a literature review, bibliography, and clinically-oriented articles. As a result of outreach by the Clearinghouse to professional organizations, the American College of Obstetricians and

Gynecologists and 11 other professional and health associations have promoted this package through their publications. This package is currently being updated.

- A booklet for medical practitioners called, "Preventing Fetal Alcohol Effects: A Practical Guide for OB/GYN Physicians and Nurses, developed by NIAAA's Clearinghouse for Alcohol Information, became available in April 1982. This booklet includes an article (by Robert J. Sokol, M.D., Sheldon I. Miller, M.D., and Susan Martier, M.S.S.A., supported in part by grants from NIAAA and NIH) setting forth practical guidelines for diagnosing alcoholism and alcohol abuse in ob/gyn patients. Fifteen thousand copies of this booklet have been disseminated to the States as part of the NIAAA national media campaign and an additional 5,000 copies through the NIAAA Clearinghouse.

A further 15,000 reprint copies now on order will be used to meet requests resulting from the efforts of the following organizations, which have agreed to promote the booklet: American Academy of Physicians' Assistants, Association of American Indian Physicians, American Indian/Alaskan Native Nurses Association, Maternal and Child Health Section of National Medical Association, National Council on Alcoholism, National Indian Health Board, American Association of Colleges of Nursing, the Public Health Service National Clearinghouse for Family Planning Information, and the Boston Women's Health Collective. Also, the following organizations agreed to announce the booklet during the Summer/Fall

1982: American College of Obstetricians and Gynecologists, American College of Nurse-Midwives, National Women's Health Network, Nurses Association of the American College of Obstetricians and Gynecologists, International Childbirth Education Association, American Public Health Association and Public Health Service Office of Adolescent Pregnancy Programs.

- A new research-oriented booklet on FAS/FAE Facts for Caregivers is currently being developed by NIAAA's Clearinghouse. It is intended to answer clinical questions of practitioners, health educators, and prevention professionals.
- NIAAA, through its Clearinghouse, is also developing a series of curriculum guides and lists of resources for use in the professional and continuing education of health professions educators. The first two of these guides (Alcohol and Drug Abuse Teaching Methodology Guide for Medical Faculty and Alcohol and Drug Abuse Curriculum Guide for Psychiatry Faculty) became available last month. Both of them list resources for teaching about fetal alcohol syndrome and effects. Several guides being developed in this series will contain entire sections on teaching about the risks of alcohol consumption during pregnancy, including the guides designed for nurse practitioner faculty, nurse faculty, pediatrics faculty, and social work faculty.

- The NIAAA Clearinghouse, as part of its Health Professions Education Program, also includes information on the fetal alcohol syndrome and effects in a package of alcohol materials designed specifically for medical and nurse educators.
- NIAAA, through its National Center for Alcohol Education, has also developed a training package entitled, "The Community Health Nurse and Alcohol-Related Problems" which contains information on the fetal alcohol syndrome.

SUMMARY

In summary, Mr. Chairman, we know some of the effects and risks of alcohol consumption during pregnancy. The risks can be eliminated. The effects can be prevented. Because a safe level of alcohol intake has not been established for the pregnant woman, we advise women who are pregnant or considering pregnancy not to drink alcoholic beverages.

We will be pleased now to answer any questions you and other Members of the Subcommittee may have.

NIAAA INFORMATION DISSEMINATION ACTIVITIES REGARDING FETAL ALCOHOL SYNDROME AND EFFECTS

June 1977	NIAAA Director, Ernest Noble, M.D. Ph.D., held a press conference announcing a "health caution" on fetal alcohol syndrome (FAS). A Critical Review of research findings on FAS was distributed at the press conference. One thousand copies were then distributed to researchers, science writers, and other persons interested in the technical aspects of the subject.
June 1977	Health caution was announced in the Center for Disease Control's Morbidity and Morality Weekly Report, which is distributed to 200,000 hospitals, clinics, public health workers and other health care professionals.
September 1977	FDA published a lead article on the fetal alcohol syndrome in the FDA Drug Bulletin, which is distributed to almost 1 million physicians, medical students, dentists, and pharmacists.
Spring 1977	This issue of NIAAA's quarterly magazine, Alcohol Health and Research World, contained a lead article on FAS. Disseminated to 5,000 subscribers; 20,000 copies of the article were reprinted to answer public inquiries.
December 1977	NIAAA published a new public education brochure, Alcohol and Your Unborn Baby, and a matching poster. To date over four million brochures and two million posters have been distributed to States, the military, maternal and child health organizations and the general public.
January 1978	NIAAA provided technical support for a syndicated storyline in the Apt. 3-G comic strip. The story, which concerned a pregnant young woman who abused alcohol, highlighted information on alcoholism as a health

	problem among women, the fetal alcohol syndrome, and where women can get help for alcoholism problems, and how families can recognize the problem. The story ran from January through June 1978. Apt. 3-G reaches 12 million readers.
March 1978	NIAAA prepared and distributed a special subject area bibliography on FAS.
April 1978	NIAAA completed a special mailing of *Alcohol and Your Unborn Baby* and poster to 77,000 obstetricians/gynecologists and family physicians. Physicians were urged to distribute the brochure to their patients.
May 1978	At the request of NIAAA, the American Medical Association and the American College of Obstetricians and Gynecologists issued an open letter to all physicians through an editorial in the American Medical News, indicating that informational material on FAS for physicians' patients was available free of charge from NIAAA. They specifically endorsed the educational campaign and asked each to make use of the brochure.
	The *FDA Consumer* published a lead article on FAS. This paid subscription magazine has a readership of 13,200. FDA subsequently reprinted 90,000 copies of the article for public distribution through the FDA Consumer Inquiries Office.
Spring 1979	The Bureau of Alcohol, Tobacco and Firearms (BATF) and the NIAAA distributed a report printed in the *Federal Register* by BATF titled "The Fetal Alcohol Syndrome Public Awareness Campaign: Progress Report Concerning the Advance Notice of Proposed Rulemaking on Warning Labels on Containers of Alcoholic Beverages and Addendum."
January 1980	NIAAA Clearinghouse began distribution of a package to technical information on FAS targeted to healthcare providers, using national healthcare providers organizations as dissemination channels. More than 5,000 packages have been distributed.

July - August 1980	NIAAA in coordination with BATF developed and implemented a national dissemination plan for a BATF-sponsored public service announcement on FAS. Depending on the preference of individual State Alcohol Authorities (SAAs), the television spot was sent to 45 SAAs for delivery to broadcast outlets and directly to 154 TV stations.
July 1980	A new brochure on FAS, using simpler language and style than Alcohol and Your Unborn Baby, was developed. Over 2 million copies of Should I Drink? have been distributed.
July 1980 - present	NIAAA awarded $1.2 million to a contractor for development of a national media campaign featuring television and radio spots and print materials, with the risks of maternal drinking for the fetus being one of the three focuses of the campaign. In the first six months, TV public service announcements were aired nearly 5,000 times, with 95% of these at the State and local level reaching a potential viewing audience of over 157 million. The campaign generated $2.5 million in free broadcast time. In 1982, States are launching their own campaigns, conducting training conferences, distributing materials, and developing a host of other activities.
September 1980	NIAAA's Clearinghouse completed an extensive outreach effort promoting Alcohol and Your Unborn Baby with 8,114 health care agencies, including community health clinics, family planning agencies, and genetic disease counseling agencies nationwide.
June 1981	Both Alcohol and Your Unborn Baby and Should I Drink? were audience tested for comprehension using the new DHHS Message Testing Service for print materials. Brochures will be revised based on results from that audience test.
July 1981	Surgeon General's Advisory on Alcohol and Pregnancy was published in FDA Drug Bulletin.
April 1982	A new booklet on identifying high-risk women, titled Preventing Fetal Alcohol Effects: A Practical Guide for Ob/Gyn Physicians and Nurses, became available through NIAAA's Clearinghouse. States received 15,000 copies as part of NIAAA's national media campaign.

Dr. **Brandt**. At this time, with your permission, we would be happy to show you these two 30-second spots, if you would like.

Senator **Humphrey**. Fine. We would be delighted.

[The following are transcriptions of the audio portions of two videotapes shown to the subcommittee.)

Videotape 1:

"I am pregnant and it sure seems like there is a lot I am not supposed to do: no smoking, watch the coffee, watch my diet, and no drinking. Alcohol can harm my baby; it can cause birth defects. So, while I am pregnant, I am not drinking. There seems to be a lot I cannot do, but then I can have a healthy child.

"For your baby's sake and yours, the safest choice is not to drink during pregnancy."

Videotape 2:

"I just delivered another healthy baby; it is a joy every time. Our medicine can do a lot to help you have a healthy baby, but not without your help. While you are pregnant, take special care of yourself, and do not drink. Alcohol can harm your baby. It can even cause birth defects.

"For baby's sake and yours, the safest choice is not to drink during pregnancy."

Dr. **Brandt**. Both of those spots, Mr. Chairman, have received fairly wide play in Washington, D.C., and I think generally around the country, and have been well received thus far.

That concludes my formal testimony. We will be pleased to answer any questions.

Senator **Humphrey**. All right, fine. Those are excellent spots and I congratulate you for them and your other work in this area of information dissemination. Yet, from my vantage point, I do not detect very much awareness yet in society as a whole of this health hazard.

How would you assess the progress being made in bringing this to the attention particularly of women of child-bearing years? It is not yet well understood, is it?

Dr. **Brandt**. Well, that is a hard question to answer, Mr. Chairman. I think that you are right; it is not as widely perceived, obviously, as it ought to be. We believe we are making significant progress, however, on the professional side of getting physicians, nurses and other health professionals aware of the problem, in the hope that they will, in dealing with patients, try to educate them.

One of the difficulties we have with that approach, of course, is that there is some evidence that alcohol does have a significant effect early in pregnancy; that is, during the first trimester, and probably even during the first month. Since not all women go to a physician for their pregnancy during the first month of pregnancy, it is clear that we have got to get the message to them.

Senator **Humphrey**. Yes.

Dr. **Brandt**. And that is why we continue to harp on the message that if you are planning on being pregnant, since you cannot tell when the moment of conception comes, you ought to quit drinking at that point in time.

Senator **Humphrey**. Yes.

Dr. **Brandt**. One group that we are particularly putting an emphasis on is teenage drinking, and we are hopeful that we can get the message across about drinking all the way. I think there is general awareness about the health effects of alcohol, but it is generally related to two things: one, alcoholism; and, two, driving.

Our approach has to be that in certain instances, there is more risk than that.

Senator HUMPHREY. I would certainly agree with that. I think almost everyone is aware of the first two dangers, but from my observation, relatively few are aware of this latter category of the danger to unborn children of drinking on the part of the mother.

I remember reading someone's full testimony—I am not sure it was yours—about the matter of the effect on pregnancy—it is hard to phrase this somehow, but what is the effect when the male partner to conception has been drinking?

Dr. BRANDT. There is no really clear evidence of teratogenic effects when the father is a drinker. Indeed, although it has been speculated by at least some people that there may be some impact on them, this is principally animal data which has suggested an association between chronic alcohol ingestion of the male with changes noted in the offspring, including altered birth weights and small litter size.

The difficulty with those studies has been one of the confounding variables, particularly nutrition, which has not been well controlled. There is no evidence that I am aware of, at least, in humans that drinking in the father leads to problems with the children—I mean of birth defects.

Senator HUMPHREY. Yes; but there is some evidence that that is the case with animals?

Dr. BRANDT. Yes, sir.

Senator HUMPHREY. So that drinking can have an effect even before conception; apparently, at least in the case of animals, some effect on the sperm and the ovum. Is that what is hinted at here?

Dr. BRANDT. Yes, sir, that is correct.

Senator HUMPHREY. Some have countered that to warn women of the dangers of drinking during pregnancy is to create stress and fear and guilt, which has perhaps an equally bad effect on the pregnancy. How do you respond to that?

Dr. BRANDT. Clearly, it seems to me that that best demonstrates the role of the physician in caring for that baby. I have no doubt in my mind that stress and guilt, in fact, can have a bad effect on the outcome of the pregnancy. After all, pregnancy is itself both physiologically and psychologically stressful.

It seems to me that it is critical to get across, again, to women and to physicians and health professionals that they must counsel women not to drink, and then the whole situation about guilt and anxiety will, in fact, not be a factor.

I might point out that stress can be reduced in the mother when she undertakes behavioral changes that she knows will increase the likelihood of having a healthy baby. Abstaining from alcohol, abstaining from smoking, a good diet and other factors of this sort can, in fact, assist her in recognizing that she is doing all she can to have a good, healthy baby.

At the same time, I think the father of the child has to play a similar role. I think during pregnancy that he has to be supportive of the fact that she should not be drinking or smoking and that her diet should be appropriate, and so forth, and assist in every way in that endeavor. It is not solely a maternal responsibility.

Senator HUMPHREY. You have stated that perhaps as many as one out of each 100 pregnancies, 1 percent, involve some abnormality; perhaps not the full fetal alcohol syndrome, but some recognizable abnormality. How have you gathered that data? That is a pretty amazing and a pretty high percentage.

Dr. BRANDT. It surprises me, also, Mr. Chairman. Let me first just make one technical correction. It is 1 in every 100 live births, not 1 of every 100 pregnancies, that is involved.

That figure comes from the estimates that have been made by studies by the Centers for Disease Control and others, and then extrapolating those data, admittedly, to the entire population, and would include even relatively minor effects, but the important thing is that they are effects.

Senator HUMPHREY. These lesser abnormalities—by that, I mean something less than the full-blown syndrome—are they generally chronic kinds of things, or are they things that a child will outgrow? Can you talk about that aspect?

Dr. MAYER. Mr. Chairman, one of the major effects, short of fetal alcohol syndrome, is diminished birth weight, and diminished birth weight subjects a child to a whole host of vulnerabilities. We know that this correlates with an increased susceptibility to infection and to diminished resistance to disease, often with metabolic problems.

So, some of these effects are not necessarily chronic effects that the child will carry all through life. But, as Dr. Brandt said, they are effects; they are measurable. They do jeopardize the ultimate good health of the child.

Senator HUMPHREY. Yes. Is that the most common example, smaller than normal size? I remember reading in someone's statement that there were frequently facial abnormalities and things of that kind, which seem to be a separate category of problems.

Dr. MAYER. Yes; there are other physical abnormalities, and there is some indication, too, that alcohol consumption during pregnancy relates to hyperactivity in childhood and other conditions which we have called neurological handicaps without being able to identify them as specific, nameable disorders. But the small birth weight is the principal effect that we are concerned with.

Senator HUMPHREY. Yes.

Dr. BRANDT. I think it is important to emphasize, Mr. Chairman, that small birth weight is a significant problem. Indeed, if you look at the efforts in this country over the past 20 years to decrease infant mortality—and I might say successfully, in that it has been cut in half during that period of time—there still remains as probably the most significant problem low birth weight, particularly weights less than 2,500 grams.

Indeed, the factors that have been related principally to the delivery of a low-birth-weight baby are as follows: one, a mother who is less than 16 years of age; second, a mother who smokes during pregnancy; third, a mother who drinks during pregnancy; and, fourth, a mother whose prenatal care is either absent or leaves something to be desired in terms of handling problems like nutrition and other inter-current illnesses.

So, a low birth weight infant is, in fact, in our judgment, a fairly significant problem.

Senator **Humphrey**. Yes; I did not mean to play that down by any means, but what I was getting at is, in the case of other kinds of problems—deformities, and so on—are they chronic, lifelong kinds of things, or how would you characterize those?

Dr. **Mayer**. In those instances in which there is an actual physical deformity, unless it is corrected surgically or in some other manner, the deformity will be a lifelong problem.

Senator **Humphrey**. You talk in your testimony on pages 7 and 8 about a test that you are developing that will identify individuals with drinking problems. What does that mean?

Dr. **Mayer**. Mr. Chairman, we are developing a method of assessing and identifying the incidence of the existence of problem drinking by utilizing data from a battery of tests that are generally available and often given in complete work-ups.

Senator **Humphrey**. Now, is this with respect to pregnant women or the whole population?

Dr. **Mayer**. Anyone. This test is applicable to anyone, not just pregnant women. Of course, it would be particularly valuable in the case of early attention to a pregnancy.

Senator **Humphrey**. Yes.

Dr. **Mayer**. The test is a computer-assisted profiling of a group of relatively standard tests which, with 85 percent or better accuracy, correctly identifies persons who have an alcohol-related problem or serious drinking problem. This would give the physician immediate signs and alerts to the necessity for intervening with great vigor in the case of a pregnant woman who showed a positive reaction.

Senator **Humphrey**. Let us touch upon the controversial issue of warning labels on alcoholic beverages. Do you have an official position? Can you talk to us about what effect you think that would have in educating the public, and so on?

Dr. **Brandt**. We have no official position, Mr. Chairman, on the issue of warning labels on alcohol, principally because we have not decided whether or not that is an effective way. If I can take a few moments, I will try and give you some of the arguments that we are weighing.

Senator **Humphrey**. Sure.

Dr. **Brandt**. Our general view about warning labels, particularly as we have used them in drugs and in cigarettes and other activities, has been that they should be part of a total educational campaign; that a warning label in and of itself is probably not going to be very effective.

So, the first thing that needs to be done is to develop a total educational campaign aimed at the problem. The second issue is that for a warning label to be effective, it clearly must be available to the person who, in fact, is going to ingest or otherwise deal with the product.

One of the difficulties with alcohol, of course, is that much of it is not consumed in that fashion; that is, it is consumed at cocktail parties, in restaurants and bars and other places, where, in fact, people do not have access to the label, much less any sort of warning label. Therefore, putting a warning label on is certainly not going to get to that group of the population.

That is in sharp contrast, again, to other products that are, in fact, required to be labeled, such as cigarettes.

Senator **Humphrey**. But at the same time, anyone who orders a drink in a bar or some establishment is likely or almost certain to have been exposed to the same product in a bottle at some point and have read that label.

Dr. **Brandt**. Well, that is possible. I do not know one way or the other about that. One would think that that is probably true.

Senator **Humphrey**. That is a reasonable assumption.

Dr. **Brandt**. Yes, that probably is a reasonable assumption. But in any event, the issue has not yet been completely decided inside the Public Health Service or in the Department of Health and Human Services at this point in time.

Senator **Humphrey**. Is there a decision date?

Dr. **Brandt**. No, sir.

Senator **Humphrey**. Are you trying to reach a conclusion on this?

Dr. **Brandt**. Yes. We are, I think it is appropriate to say, struggling with the problem in an attempt to come to a conclusion.

Senator **Humphrey**. All right. Now, is there any distinction between kinds of alcoholic drinks and their effect? Can you talk about that a little bit?

Dr. **Brandt**. There has been one study reported that showed a greater likelihood of trouble with beer than with so-called distilled spirits.

Senator **Humphrey**. Really?

Dr. **Brandt**. I think that the overwhelming volume of evidence is that alcohol is alcohol; that there is no difference in drinking beer or wine or distilled spirits in terms of the risk of the fetus, because it is the alcohol and 1 ounce of alcohol is 1 ounce of alcohol, irrespective of how it is packaged.

I might point out that there are other products in the marketplace that are not ordinarily sold for this purpose that do contain alcohol—certain tonics and other sorts of over-the-counter activities.

Senator **Humphrey**. What was that you mentioned?

Dr. **Brandt**. Certain kinds of tonics, certain types of flavorings for food, and so forth, that do contain alcohol. As far as we can determine, that alcohol is just as harmful as alcohol that one gets in distilled spirits.

So, in our view, we know of no difference between different kinds of drinks in terms of alcohol exposure. I might point out that that is also true of driving.

Senator **Humphrey**. I missed the last word. I am an old, brokendown pilot.

Dr. **Brandt**. That is also true of the effect on driving.

Senator **Humphrey**. Driving, yes.

Dr. **Brandt**. We have not been able to tell any difference between wine, beer, and distilled spirits.

Senator **Humphrey**. Can you give us some rule of thumb about the alcoholic content of the various popular beverages?

Dr. **Brandt**. I have it here and if you will allow me one moment, I will find it for you, sir.

Dr. **Mayer**. Mr. Chairman, it is interesting to note that the way people drink results generally, regardless of the drink that they choose, in approximately the same amount of alcohol if a conventional drink is consumed.

Senator **Humphrey**. Yes.

Dr. **Mayer**. So, a standard drink of distilled spirits is about an ounce-and-a-half. If it is 80 proof spirits, it contains about six-tenths of an ounce of chemically pure alcohol.

Senator **Humphrey**. One cocktail?

Dr. **Mayer**. One cocktail, one mixed drink, one shot glass full of distilled spirits. By the same token, a 5-ounce glass of wine, a modest-sized glass of wine, also contains six-tenths of 1 ounce, and a 12-ounce can of beer contains just slightly less, but still more than one-half of 1 ounce of absolute alcohol.

This is why we in the Department and in the agency consistently state the fact that alcohol is alcohol, regardless of the vehicle you take it in with, because people generally do not drink a shot glass full of beer; they drink a standard-sized beer.

Senator **Humphrey**. So, there is no escaping it. You cannot really ameliorate the effects by switching beverages.

OK, fine. Thank you for your excellent testimony this morning. It was a pleasure to have you here.

Dr. **Brandt**. Thank you very much for the opportunity.

Senator **Humphrey**. Our next panel is comprised of Dr. Jon Aase, associate professor of pediatrics, University of New Mexico; Dr. Ruth Little, director of the Alcoholism and Drug Abuse Institute at the University of Washington; Dr. LeClair Bissell and Dr. Jokichi Takamine of the American Medical Association; Dr. Sheila Blume, National Council on Alcoholism; and Dr. Sergio Fabro of the American College of Obstetricians and Gynecologists.

Good morning. I am afraid I am going to have to ask each of you to summarize your testimony. Of course, the full statements of all of our witnesses this morning, will be included in the record.

Let us begin from your right to left? Dr. Fabro?

STATEMENT OF SERGIO E. FABRO, PROFESSOR OF OBSTETRICS AND GYNECOLOGY AND PHARMACOLOGY, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, REPRESENTING THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS; SHEILA B. BLUME, DIRECTOR, NEW YORK STATE DIVISION OF ALCOHOLISM AND ALCOHOL ABUSE, REPRESENTING THE NATIONAL COUNCIL ON ALCOHOLISM, INC., AND THE AMERICAN MEDICAL SOCIETY ON ALCOHOLISM; LeCLAIR BISSELL, MEMBER, PANEL ON ALCOHOLISM, AMERICAN MEDICAL ASSOCIATION, AND JOKICHI TAKAMINE, MEMBER, PANEL ON ALCOHOLISM, AMERICAN MEDICAL ASSOCIATION, ACCOMPANIED BY ROSS RUBIN, DIRECTOR, DEPARTMENT OF FEDERAL LEGISLATION, AMERICAN MEDICAL ASSOCIATION; RUTH E. LITTLE, DIRECTOR, ALCOHOLISM AND DRUG ABUSE INSTITUTE, UNIVERSITY OF WASHINGTON; AND JON M. AASE, ASSOCIATE PROFESSOR OF PEDIATRICS, UNIVERSITY OF NEW MEXICO, A PANEL

Dr. **Fabro**. Mr. Chairman——

Senator HUMPHREY. Be sure to pull the microphone to you when it comes your turn, if you will.

Dr. FABRO. Mr. Chairman, thank you for inviting me to participate in this hearing. In your letter, you invited me to comment on three specific and distinct areas in relation to alcoholic beverage consumption and pregnancy outcome.

The three areas are: One, the position of the American College of Obstetricians and Gynecologists in this matter; two, my personal opinion, based on my scientific involvement and perspective in this area; and three, the obstetrician's role in counseling patients on fetal alcohol effects. I would like, with your permission, to maintain my comments in the three different areas well separated, since different considerations apply to each.

The position of the American College of Obstetricians and Gynecologists is clear and well defined. In a statement of policy, approved and issued by the executive board on alcohol and pregnancy, it is stated:

> Ample clinical and experimental evidence exists to demonstrate that chronic, excessive consumption of alcohol during pregnancy is associated with a variety of congenital malformations and other defects. At the present time, there is not sufficient evidence to substantiate or refute that moderate intake of alcohol is harmful to the fetus.

This statement, made in 1977, is still scientifically valid in 1982. The characteristics of the human fetal alcohol syndrome have been comprehensively described, as have the effects of alcohol on pregnancy in several animal models. Our knowledge is still incomplete and attention is now being focused on several critical questions, one of the most controversial being, How much alcohol consumption constitutes a real risk to the fetus?

Some investigators believe that even small amounts of alcohol may be harmful, while others believe that adverse effects are only induced following consistent, heavy drinking. In fact, there are three hypotheses regarding a dose-effect relationship for alcohol consumption and human health in general. Let us call these hypotheses A, B, and C, as they are presented graphically here.

Here, we are looking at increasing levels of alcohol intake on the X axis, and on the Y axis, the effect on human health—negative here, or detrimental; positive here, or beneficial [indicating].

Now, all three hypotheses are in agreement that continuous drinking in high doses represents a hazard to human health, and this is also scientifically correct as far as the human fetus is concerned. However, the three hypotheses differ when it comes to assessing the health impact of moderate or low doses of alcohol.

Scientists who favor hypothesis A believe that no matter how small daily intake of alcohol is, there is a corresponding detrimental effect on human health. This is called the "straight-line hypothesis," in which it is implied that only by avoiding alcohol consumption entirely is it possible to avoid entirely alcohol-induced harmful effects.

In contrast, hypothesis B indicates that there is a level of daily intake of alcohol below which there is no effect, either harmful or beneficial, on human health. In the graph, the arrows indicate the so-called threshold doses and this hypothesis is called the threshold hypothesis.

There are other investigators—and some scientific data are available—who believe that hypothesis C accurately reflects the relationship between alcohol and human health effects. As you can see from the graph, not only is there a threshold dose for adverse ethanol effects, but also daily intakes of alcohol which are smaller than the threshold dose would have beneficial effects.

As far as the human fetus is concerned, there is no definite evidence as to which of these three hypotheses is the valid one. However, in the last 5 years or so, scientific evidence has been accumulating from which an argument for hypothesis B, the threshold hypothesis, can be constructed.

To this end, I would like to briefly summarize a myriad of experimental data in conjunction with the human experience. First, general principles established from extensive laboratory animal experimentation hold that threshold phenomena are a usual feature of embryotoxic responses.

In the case of alcohol in experimental animals, some apparent threshold values have been established for specific effects. For the human child, adverse effects of maternal alcohol consumption during pregnancy appear to follow standard dose-response relationships, although current data are incomplete.

Although no-effect levels in the human have not been established, it is likely that a range of different threshold doses exists, depending upon the end point considered, the drinking pattern, and the genetic characteristics of the individual.

A detailed description of available data and references to publications in this area can be found in a report I prepared for the Department of the Treasury in 1979. In addition, we have recently reviewed this issue at the Reproductive Toxicology Center, and updated information in this area can be found in a recent issue of the medical letter, "Reproductive Toxicology," a copy of which I have attached to my written testimony.

Let me now turn to the subject of the obstetrician's role in counseling patients as to the effects of alcohol consumption during pregnancy. In my opinion, obstetricians and gynecologists have an important role in conveying the correct information to patients who are pregnant or who are planning to become pregnant.

In my experience, the last 10 years have witnessed an increasing awareness and concern on the part of obstetricians and gynecologists as to problems related to the potential harmful effects of the environment in general on pregnancy outcome.

The increasing attention to this subject is indicated by the number of specialized postgraduate courses for continuing medical education, books, and specialized information services.

As far as the problem of alcohol and pregnancy is concerned, the obstetrician's role is fairly straightforward. In the relatively rare situation in which a patient is a nondrinker, then the obstetrician's role is to stress to the patient that since it is not known what effect low doses of alcohol may have, it is better not to drink during pregnancy.

However, most of the time patients report that they drank in moderation in early pregnancy before they knew that they were pregnant. To this patient, my counsel is that the threshold hypothesis is likely to exist, and that it is very unlikely that the type of drinking they did will have a significant harmful effect on their baby. This relieves feelings of anxiety, which, in animals, is itself associated with poor pregnancy outcomes.

Mr. Chairman, I hope I have satisfactorily outlined the three areas which I was invited to comment on. Thank you very much for the opportunity.

[The prepared statement of Dr. Fabro with attachment follows:]

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September 21, 1982

The Honorable Gordon J. Humphrey
Chairman, Subcommittee on Alcoholism
and Drug Abuse
United States Senate
Washington, D.C. 20510

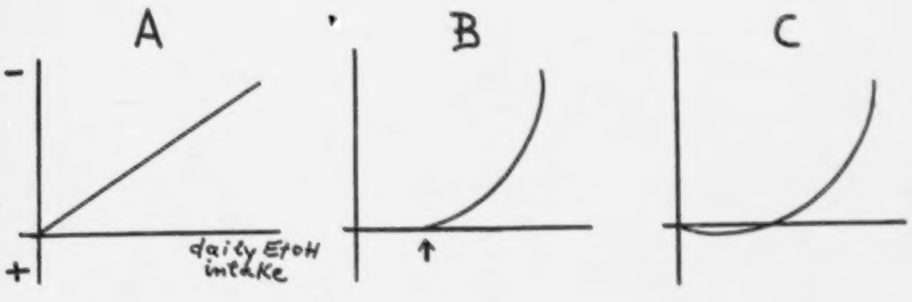
Dear Mr. Chairman:

Thank you for inviting me to participate in this hearing of the Subcommittee on Alcoholism and Drug Abuse. In your letter of September 10, 1982 you invited my comments on three specific and distinct areas in relation to alcoholic beverage consumption and pregnancy outcome. These three areas are: 1) The position of the American College of Obstetricians and Gynecologists in this matter, 2) My personal opinion, based on my scientific involvement and perspectives in this area, and 3) the obstetrician's role in counseling patients on fetal alcohol effects. I would like, with your permission, to maintain my comments in the three different areas well separated, since different considerations apply to each.

The position of the American College of Obstetricians and Gynecologists is clear and well defined. In a statement of policy approved and issued by the Executive Board on alcohol and pregnancy, it is stated that: "Ample clinical and experimental evidence exists to demonstrate that chronic, excessive consumption of alcohol during pregnancy is associated with a variety of congenital malformations and other defects.

At the present time there is not sufficient evidence to substantiate or refute that moderate intake of alcohol is harmful to the fetus."

This statement, made in 1977, is still scientifically valid in 1982. The characteristics of the human fetal alcohol syndrome (FAS) have been comprehensively described, as have the effects of alcohol on pregnancy in several animal models. Our knowledge is still incomplete, and attention is now being focused on several critical questions, one of the most controversial being: How much alcohol consumption constitutes a real risk to the fetus? Some investigators believe that even small amounts of alcohol may be harmful, while others believe that adverse effects are only induced following consistent heavy drinking. In fact, there are 3 hypotheses regarding a dose-effect relationship for alcohol consumption and human health in general. Let's call these "hypotheses A, B and C", and they are presented graphically in the figure.



Here we are looking at increasing levels of daily alcohol intake on the X-axis in the three graphs; the Y-axis indicates the degree of effect on human health, which can be either a negative - or harmful- or positive - beneficial. Now, all three hypotheses are in agreement that continuos daily intake of alcohol in high doses are harmful to human health, and this also appears to be a scientifically correct assessment for the human fetus. However, the 3 hypotheses differ when it comes to assessing the health impact of moderate or low daily consumption of ethanol. Scientists who favor hypothesis A believe that no matter how small daily intake of alcohol is, there is a corresponding detrimental effect on human health. This is called the "straight-line hypothesis", in which it is implied that only by avoiding alcohol consumption entirely is it possible to avoid entirely alcohol-induced harmful effects.

In contrast, hypothesis B indicates that there is a level of daily intake of alcohol below which there is no effect, either harmful or beneficial, on human health. This is called the "threshold hypothesis". In the graph, the arrow indicates the so-called threshold dose, the level of alcohol consumption where adverse effects begin to be detectable. There are other investigators, and some scientific data are available, who believe that hypothesis C accurately reflects the relationship between alcohol and human health effects. As you can see from the graph, not only is there a threshold dose for adverse ethanol effects, but also daily intake of alcohol in amounts smaller than the threshold dose would have beneficial effects. As far as the human fetus is concerned, there is no definite evidence as to which of these three hypotheses is the valid one. However, in the last 5 years or so scientific evidence has been accumulating from which an argument for hypothesis B (the threshold hypothesis) can be constructed.

To this end, I would like to briefly summarize a miriad of experimental data in conjunction with the human experience.

General principles, established from extensive laboratory animal experimentation, hold that threshold phenomena are usual feature of embryotoxic responses.

In the case of alcohol in experimental animals, some apparent threshold values have been established for specific end-points.

For the human child, adverse effects of maternal alcohol consumption during pregnancy appear to follow standard dose-response relationships, although current data are incomplete.

Although no-effect levels in the human have not been established, it is likely that a range of different threshold doses exist, depending upon the end-point, the drinking pattern, and genetic characteristics.

A detailed description of available data and references to publications in this area can be found in a report I prepared for the Department of the Treasury in 1979 (1). In addition, we have recently reviewed this issue at the Reproductive Toxicology Center and updated information in this area can be found in a recent issue of the Medical Letter - Reproductive Toxicology - (2).

Let me now turn to the subject of the obstetricians' role in counseling patients as to the effects of alcohol consumption during pregnancy. In my opinion, obstetricians and gynecologists have an important role in conveying the correct information to patients who are pregnant or who are planning to become pregnant in the near future. In my experience, the last 10 years have witnessed an increasing awareness and concern on the part of obstetricians and gynecologists as to problems related to the potential harmful effects of the environment in general on pregnancy outcome. The increasing attention to this subject is indicated by the number of specialized post-graduate courses for continuing medical education, books and specialized information services. As far as the problem of alcohol and pregnancy is concerned, the obstetricians' role is fairly straight-forward. In the relatively rare situation in which a patient is a teetotaller, then the obstetricians role is to stress to the patient that since it is not known what effect low doses of alcohol may have, it is better not to drink during pregnancy. However, most of the time patients report that they drank in moderation in early pregnancy before they knew they were pregnant. To these patients, my counsel is that the threshold hypothesis is likely to exist, and that it is very unlikely that that type of drinking they did will have a harmful effect on their babies. This relieves feelings of anxiety, which (in animals) is itself associated with poor pregnancy outcome. Mr. Chairman, I hope that I have satisfactorily outlined the three areas which I was invited to comment on. Thank you very much for giving me the opportunity of appearing before your subcommittee.

Yours truly,

Sergio Fabro

Sergio E. Fabro, M.D., Ph.D.
Professor of Obstetrics and
Gynecology and Pharmacology

References:

1) S. Fabro: "Alcoholic Beverage Consumption and Outcome of Pregnancy". In The Fetal Alcohol Syndrome-Public Awareness Campaign; The Department of the Treasury. February 1979; p.37-199.

2) Reproductive Toxicology - A Medical Letter; Vol. I, No. 3., 1982. In Utero Alcohol Exposure: Threshold for Effects?

REPRODUCTIVE TOXICOLOGY
a medical letter

on Environmental Hazards to Reproduction

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IN UTERO ALCOHOL EXPOSURE: THRESHOLD FOR EFFECTS?

The characteristics of the human Fetal Alcohol Syndrome (FAS) have been comprehensively described, as have the actions of alcohol on pregnancy in several animal models. Attention is now focused on several critical questions, one of the most controversial being: How much alcohol consumption constitutes a real risk to the fetus? Some investigators believe that small amounts of alcohol may be hazardous, while others consider that adverse effects are only induced following consistent heavy drinking. The argument distils to: Is there a threshold dose for ethanol embryotoxicity?

ANIMAL STUDIES — In typical studies using laboratory animals, intra-uterine death and/or malformation are the end-points used to assess the effects of gestational exposure to an agent. Extensive testing, using a wide variety of chemicals, demonstrates that a no-effect level is usually observed, providing that a suitable range of doses is used. In other words, a threshold dose exists, below which no statistically significant excess of malformations or fetal death is observed. The same appears to hold for growth-retardation, although this effect has been less widely studied. Behavioral or functional effects of *in utero* exposure have not been widely enough studied to make a general statement on dose-response relationships. For the different types of embryotoxicity (i.e. death, malformation and retardation), different threshold doses are generally observed, even when each effect is induced by the same agent. Often, a low dose will retard growth, a larger dose will induce structural changes and a high dose may result in embryonic death.

Such a pattern of responses has been observed in several studies of ethanol embryotoxicity, but careful dose-response investigations specifically designed to estimate threshold doses are relatively limited. Effective doses vary considerably in these studies, depending upon the species used, the route of ethanol administration and the dosage regimen. A large dose of ethanol administered on one day of gestation is claimed to be a model for binge drinking in pregnancy. Single doses of 3–6g/Kg to mice via the intraperitoneal (i.p.) route can lead to malformations (Webster et al, Neurobehav. Toxicol., 2, 227, 1980; Sulik et al, Science *214*, 939, 1981). In other studies, single oral (intragastric intubation) doses of 5g/Kg to mice have not led to malformations, although 2.5g/Kg and greater can reduce birth weight (Lochry et al, Neurobehav. Toxicol. *4*, 15, 1982).

Exposure of animals to ethanol each day, throughout gestation, may mimic steady drinking in human pregnancy. For mice, the maximum daily dose of alcohol which can be tolerated when given by the intragastric route is about 6g/Kg, unless stressful multiple intubations are used. In contrast, daily doses of at least 15g/Kg can be tolerated if an ethanol solution is presented as the sole fluid source, and up to 30g/Kg/day can be consumed if ethanol is included as part of a liquid diet. Malformation and growth retardation have been observed following gestational alcohol exposure by each of these routes, with effective doses normally falling in the range of 50% to 100% of the maximum tolerated dose. As examples, dose-related increases in malformation rates are

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observed in the offspring of mice fed isocaloric liquid diets containing 20–30% ethanol-derived calories, equivalent to about 15 to 25g/Kg/day (Randall et al, Subst. & Alc. Actn./Misuse, 2, 349, 1981). Beagle bitches fed ethanol by two daily intragastric intubations experience various adverse outcomes of pregnancy in a dose-dependent manner with doses exceeding 2.4g/Kg/day (Ellis and Pick, Alcoholism, 4, 123, 1980).

The performance of offspring in many behavioral tests has been evaluated following maternal alcohol treatment throughout pregnancy (see Abel, ed., The Fetal Alcohol Syndrome, Vol III, CRC Press, 1982, p. 59). Most of these studies have used the rat. Doses of about 4g/Kg/day (by intubation or injection) affect shock avoidance, passive avoidance and activity/curiosity in offspring. Chronic maternal administration of 2g/Kg/day or less generally is not associated with altered offspring behavior.

Regardless of the structural, growth or behavioral end-point measured on the offspring, very few studies have demonstrated any statistically significant effect of maternal exposure to less than 2g/Kg/day ethanol, by any route of administration, in any experimental species.

Differences in response, depending upon route and regimen, are likely to be due to disparate ethanol pharmacokinetics in the dam. A single oral ethanol dose of 5g/Kg to mice may lead to peak blood alcohol concentrations (BAC) of 300mg%, but levels fall to close to zero within a few hours. In contrast, mice consuming 15g ethanol/day in a liquid diet may maintain BAC of about 100mg% throughout the day. Thus, comparisons between studies based upon equivalent BAC, rather than doses, may be more accurate. However, time course of BAC may be as important, since it is likely that embryonic response reflects the integral of dose and period of exposure. Based upon data from several species, it has been suggested that chronic BAC below 150mg% have only minimal effects on birth weight, while levels between 150–200 mg% produce birth weight reductions of 10 to 14% (Abel, op. cit., p. 54).

Species and strain differences in response to *in utero* ethanol exposure are commonly observed and suggest a genetic component to the toxicity (see Riley and Lochry, in Abel op. cit., p. 113). Although some of these differences are due to disparate physiological disposition of ethanol, affecting BAC as above, others appear to reflect intrinsic differences in sensitivity to ethanol between strains or species.

HUMAN STUDIES — An accurate estimate of dose administered is an obvious prerequisite for meaningful dose-response analysis. This is a particularly difficult task for human alcohol intake, since information given by the subject may not be reliable, many types of beverage are involved, and drinking patterns vary widely. Several methods of describing alcohol intake have been proposed, none are universally accepted and it should not be expected that a single number can adequately describe both steady daily consumption and episodic binge-drinking.

Currently, alcohol intake is normally expressed as an average amount of absolute alcohol (AA) consumed per day. Servings of beverages are assumed to be a constant size, typically: beer, 12oz; wine, 5oz and hard liquor 1.25oz and to contain a constant proportion of ethanol by volume, say 4%, 12%, and 45% respectively. Thus, one drink of beer, wine or liquor would contain about 0.5, 0.6, 0.6oz (12, 14, and 14g) AA, respectively. As a first approximation then, one drink is 0.5oz AA and 5 drinks/day for a 60Kg person is about 1g/Kg/day.

Ethanol distributes throughout total body water, which is approximately 50% of body weight. Thus, a dose of 1g/Kg, if it were instantly absorbed and equally distributed, would yield a BAC of 200mg%.However, ingestion, absorption, and distribution are not instantaneous and ethanol is quite rapidly metabolized. In fact, 1g/Kg (5 drinks/60Kg person) drunk within one hour will lead to peak BAC of about 120–160mg% which will fall at a rate of about 20mg%/hour.

Despite the complexity of prenatal alcohol abuse in the human, current data on embryo-fetal ethanol effects are compatible with a typical pattern of increasingly severe manifestations of toxicity with increasing dose. Case studies and epidemiological surveys clearly show that the full syndrome of FAS, including typical malformations, is only observed in the offspring of chronic alcoholic mothers. Prospective studies of the general population show that heavy drinking is also associated with adverse outcomes of pregnancy. In one study, the offspring of heavy-drinking mothers (group mean 5.8oz AA/day [2.2g/Kg/day]) had a 2–3 times higher incidence of congenital malformations and functional anomalies, compared to moderate or rare drinkers (Rosett et al, Ob-Gyn, *51*, 41, 1978). It is not clear if lesser amounts of alcohol can also induce structural malformations. It has been suggested that features consistent with FAS can be observed in the offspring of mothers consuming 1–2oz AA/day (Hanson et al, J. Pediatr. 92, 457, 1978). However, there was no distinction between structural defects and growth reductions in this study's definition of features of FAS.

Birth weight reduction may be induced at lower doses of alcohol than those which induce specific dysmorphology. In a Paris study, offspring of women drinking at least 1.6oz AA/day (0.6g/Kg/day) were an average of 59g lighter than offspring of light drinkers (Kaminski et al, see Alcoholism, *2*, 155, 1978). In a Seattle study (Little, Am. J. Pub. Health, *67*, 1154, 1977) an average decrement of 160g was observed for the offspring of women who consumed at least 1oz AA/day (0.4g/Kg/day). It is a major failing of these studies that women ingesting very different amounts of alcohol, from moderate (about 1oz/day) to heavy (greater than 4oz/day), were all considered as one group.

A wide variety of postnatal behavioral effects of maternal alcohol consumption have been documented (see Streissguth et al, Science, *209*, 353, 1980). However, studies have focused primarily on characterization of the functional deficits of FAS children and the offspring of heavy drinkers. The effects of lower amounts of alcohol are not well documented. Bayley mental and motor scores of infants at 8 months do not seem to be affected in offspring of mothers who drank less than 4oz AA/day (1.6g/Kg/day), but studies are limited and the dose-response for more subtle changes have not been established (Streissguth et al, Alcoholism, *4*, 152, 1980).

Inter-individual and inter-ethnic variations in ethanol-induced effects are well established. These may be due to differences in ethanol pharmacokinetics; for example, persons of Eskimo and American Indian origin have slower rates of alcohol metabolism than Caucasians. Within any given ethnic group, rates of ethanol metabolism can vary widely in a manner which is predominantly under hereditary, rather than environmental, control. Differences in ethanol response can also be due to disparate sensitivities. The best known example in man is that of persons of Asian origin who are more sensitive to the facial flushing and increases in pulse pressure induced by alcohol, than are Caucasians. At this time, there are no proven examples of genetic predisposition to FAS.

CONCLUSIONS — General principles, established from extensive laboratory animal experimentation, hold that threshold phenomena are a usual feature of embryotoxic responses. Different thresholds are likely to exist for different end-points; for the same agent applied to animals of different genetic backgrounds; or for the same dose given by disparate routes or regimens.

In the case of alcohol in experimental animals, some apparent threshold values have been established for specific end-points, in specific strains, following stated modes of alcohol administration. For example, 2.4g/Kg/day in two daily doses by gastric intubation may be the threshold for an increase in stillbirths and a reduction in perinatal survival in beagle dogs (Ellis and Pick, op.cit.).

For the human child, adverse effects of maternal alcohol consumption during pregnancy appear to follow standard dose-response relationships, although current data are incomplete. The full Fetal Alcohol Syndrome has only been observed in the offspring of chronic alcoholic mothers, who generally consume at least 5oz AA every day (about 2g/Kg/day). However, other effects are clearly induced with lesser alcohol intake. For example, birth weight reduction may be a consequence of daily consumption of 2–3oz AA/day throughout pregnancy. There is currently no evidence for any adverse effects associated with light alcohol consumption, for example one glass of wine each day (0.5oz AA/day).

Although no-effect levels in the human have not been established, it is likely that a range of different threshold doses exist, depending upon the end-point, the drinking pattern, and genetic characteristics. It is also not known if there are periods of gestation during which the embryo is particularly sensitive to ethanol effects. Similarly, it is not known if different patterns of drinking, for example binge drinking or steady chronic consumption, produce different effects on prenatal development. Humans are genetically diverse and differences in alcohol metabolism and sensitivity are known. It is likely that such genetic differences influence the threshold doses for ethanol effects on embryo-fetal development. At this time, genetic predisposition to FAS in humans has not been described.

NEW BOOKS

Drug Use in Pregnancy (Ed. J. R. Niebyl, 194 pp., pub. Lea & Febinger, 1982, $18.50) and *Drug Therapy in Obstetrics and Gynecology* (Ed. W. F. Rayburn and F. P. Zuspan, 401 pp., pub. Appleton-Century-Crofts, 1982, $38.50).

Aimed at the practicing Obstetrician and Gynecologist, these two texts are further signs of the increasing awareness that the use of drugs in OB/GYN requires specific therapeutic and toxicologic expertise. *Drug Use in Pregnancy* is a multi-authored text derived from a post-graduate course held at Johns Hopkins University. In 14 chapters, the monograph reviews the literature concerning the efficacy and potential hazards of various drugs in pregnancy, perinatal drug use, and the toxicities of narcotic addiction, alcohol, caffeine and cigarettes in pregnancy.

About half of the contributions conclude with a final 'recommendations' section, which concisely summarizes current knowledge and gives specific advice on therapy. Other high-points of the book are the chapters on smoking and on narcotic addiction, both of which give specific advice on patient management; a well-balanced commentary on drugs for pregnancy-induced nausea and vomiting, and the reviews of tocolytics, antiasthmatics and antibiotics. It is never possible to satisfy all the people all the time, but it is perhaps surprising that some classes of drugs commonly encountered in pregnancy (e.g. sedatives, anesthetics, anticonvulsants, hormones) are not covered, while some less used drugs (antineoplastics, anticoagulants) receive extensive coverage.

Drug Use in Pregnancy is a timely publication and should be most useful for those seeking a clinically-based review of the field. Anyone contemplating the initiation of an advanced course in this area should also consider this text as a sound starting-point.

Drug Therapy in Obstetrics and Gynecology is a larger, more ambitious publication that aims to provide information on specific drugs which are used in daily OB/GYN clinical practice. Using an excellent text design, the book is divided into three sections: Obstetrics, Gynecology and Drugs for General Use. There are overview chapters on Drug Effects on the Fetus, Principles of Perinatal Pharmacology and Drugs in Breast Milk, with the remaining 23 chapters dealing with individual classes of drugs, or the therapy of specific conditions.

Although there is a little variation in format from chapter to chapter, each contribution includes a summary of the basic pharmacology involved, indications for drug use, doses and dosage regimens and appropriate precautions. These subjects are reviewed in a clear and concise manner with the liberal use of comprehensive summary tables. Each chapter ends with a thorough, but relevant, bibliography for more in-depth information. There are, in addition, three useful appendices concerning chemical properties of drugs, cost comparisons and adverse interactions.

Drug Therapy in Obstetrics and Gynecology should be invaluable to practicing physicians in the field and is well suited as a text for training. It succeeds admirably in presenting the concept that therapeutics in Obstetrics and Gynecology requires special considerations not found in traditional textbooks of pharmacology.

REPRODUCTIVE TOXICOLOGY, a Medical Letter
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Editor: **Sergio Fabro, M.D., Ph.D.** Associate Editor: **Nigel A. Brown, Ph.D.**

Senator Humphrey. Thank you, Dr. Fabro. We will have questions for you. I think it is best to go through and get statements first.

Good morning, Dr. Blume.

Dr. Blume. Good morning. I am Sheila Blume, director of the New York State Division of Alcoholism and Alcohol Abuse, and a physician with 20 years' experience in treating alcohol problems. As State director, I headed a statewide Governor's task force on fetal alcohol syndrome, the report of which you have, and you also have a packet of our public and professional education materials in front of you.

I would also like to mention that an evaluation of that project is in its final stages of completion by Dr. Marcia Russell of our Research Institute on Alcoholism in Buffalo, where she polled 500 practicing obstetrician-gynecologists, and as soon as that report is prepared, I will be glad to supply it.

Senator Humphrey. Thank you.

Dr. Blume. I am here to testify today not as a State official, but as a volunteer, a member of the board of directors of the National Council on Alcoholism, and a past president of the American Medical Society on Alcoholism.

NCA was quick to recognize the public health implications of the early research on alcohol-related birth defects and took an active role as early as 1971 in convening the first conference in which FAS was described to scientists in the United States, and shortly afterward began to award research awards in this area.

Reports of research already completed and preliminary data from studies in progress, both human and animal, in our view, clearly establish the teratogenic effects of alcohol. Of course, more research is definitely needed and I list seven points that we consider are the most important ones that need new knowledge.

NCA and AMSA strongly support continued Federal funding for this research and we applaud President Reagan's request to increase the Federal alcoholism research effort by over 50 percent in 1983.

However, armed with the information currently available, we feel we have now before us an unparalleled opportunity for prevention, as you said in your opening remarks. For example, in New York State we calculated that the infants born with alcohol-related birth defects in a single year, the year 1978, will cost society a total of $155 million in additional lifetime care due to these birth defects. It is an expensive problem.

In order to accomplish this prevention, there are two groups of women of child-bearing age which we must reach. First are the women who are free of alcohol problems and who can benefit from public information and the kind of advice that we just heard about.

The second group, however, are those women who are suffering from alcoholism or are alcohol abusers, who cannot be helped by information alone. A subgroup which needs special attention is teenage girls. There are over 1.1 million teen pregnancies a year in this country. According to a 1978 Research Triangle Institute study, 9 percent of high school girls were classified as heavy drinkers, meaning that they drink at least five drinks at a time at least once a week. When you put those statistics together, you see that you have a population that is at important risk.

Both women who drink without problems and those who are alcoholics need information about the risks to the fetus about drinking during pregnancy. But the latter group of women will also require help in identifying their alcohol problems, and will require treatment to overcome them.

To reach both of these groups, the following components are required as a minimum: Public education; professional education; simple, practical, and effective systems for the routine screening, identification and referral of problem drinkers in all obstetric practices; effective and accessible treatment services for alcoholic women and their families which can take advantage of the desire of the pregnant woman to bear a normal child as an aid in motivation for her alcoholism treatment; and, finally, effective identification and treatment services for those infants and children who are suffering from fetal alcohol effects.

I would like to comment on the first three of those minimum, necessary requirements. Public education is first. There are a number of effective approaches to informing the public. We felt that the Surgeon General's advisory warning women not to drink if they are pregnant was one of the most important of these initiatives and one which NCA both approves and applauds.

Major efforts have been made by private and voluntary organizations, such as the alcoholic beverage industry and the March of Dimes. I handed up an example by the Will Rogers Institute, which sends messages to movie theaters all over the country. Movie theaters have a young audience. It stars Rita Moreno and you have it there.

Senator HUMPHREY. If we could only put them on video games, then we would really take a giant step.

Dr. BLUME. That is the next place. I had not thought of that.

NIAAA and BATF have produced materials which we saw just now. NCA and AMSA believe that the most effective public message will be one that is both direct and accurate, which neither exaggerates nor downplays the risk of damage. By "direct," we mean directly stating the fact that alcohol can be toxic to the fetus. We feel that messages that simply say "ask your doctor" are not sufficient, because many women do not receive adequate medical care and many, as you pointed out, do not receive this care early in pregnancy for economical or other reasons. A significant number of these women and girls, many of them teenagers, are at high risk.

NCA and AMSA strongly recommend that the Federal Government not give up its public education initiatives. On the other hand, we think they should be strengthened. We also strongly recommend Federal action to require health warning labels on beverage alcohol containers. I have attached to the testimony policy statements from both organizations in support of that.

We feel that public information campaigns, by their very nature, are time-limited. The warning label, on the other hand, is one way to assure ongoing information about the dangers of alcohol to the fetus, and make it part of our general knowledge so that every person in this country knows that alcohol is not good for the fetus just as he knows that if you eat too much, you are going to get fat.

Second, professional education: Not only is there a need for education concerning the teratogenic effects of alcohol, but, more important, training in the skills necessary to identify alcoholism and to intervene effectively is critical to preventing FAS. As I have mentioned, information alone cannot help a woman suffering from alcoholism.

The Federal Government can help by continuing to support both needed research and the means for its dissemination. Also, direct programs, such as the support of alcoholism teaching and family practice departments in medical schools, and particularly the career teachers program, have made an enormous difference in medical education. We appeal for the continuation of these excellent efforts.

Third and last, I would like to talk about practical systems for identifying alcohol problems in obstetrical practice. It should be part of the routine health care of every American woman, and most especially for a woman receiving obstetric care, that a careful history be taken of her alcohol intake, and any alcohol-related problems be investigated.

Those with problems should be routinely and adequately referred for treatment and followup. Unfortunately, it is my experience that this is not the case today, in spite of the fact that, for example, an obstetrical clinic in Buffalo, N.Y., found an incidence of 3 percent—that is, 1 out of every 33 women coming for prenatal care—reported an average of 6 drinks of alcohol per day, everyday, putting her at high risk for fetal alcohol syndrome. An additional 4 percent reported having 6 or more drinks per day on the days in which they drank.

Alcohol problem identification today rests primarily with individual practitioners, most of whom unfortunately are not adequately trained for this task. The previously mentioned survey by Dr. Russell found that 40 percent of obstetrician-gynecologists polled—that is, in New York State—referred no patients for the treatment of drinking problems during the past year. Of those, by the way, only 6 percent of the 40 percent said they had identified none.

There is an urgent need, in our opinion, to develop simple, practical, workable systems which can be adapted to different obstetric settings, and to develop strategies to stimulate their adoption nationwide. Various models of such systems have already been developed but are not widely used. We recommend that the Surgeon General, with the cooperation of the Congress, convene a task force made up of recognized leaders in the field of obstetrics, pediatrics, public health, family medicine, psychiatry and alcoholism, representatives of the American Medical Association, the American Nurses Association, and American Hospital Association, to review present efforts; recommend workable, practical systems; and, most important, to develop a strategy to promote implementation of such systems in every community in the Nation.

We believe that only the Federal Government has the breadth and scope of public health responsibility to undertake such an effort and to make it work. It is an opportunity for the Federal Government to bring together the private and public sectors to achieve what no one organization, State or medical speciality can possibly accomplish. Of course, we at NCA and AMSA stand ready to help in this kind of an undertaking in any way we can.

In conclusion, today we are faced with a unique opportunity to achieve prevention of human suffering and disability, but a great deal of work remains to be done before that can be accomplished. I hope you will seriously consider our recommendations and that you will take us up on our offer of help.

Thank you.

[The prepared statement of Dr. Blume follows:]

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WALTER J. MURPHY
Executive Director

STATEMENT OF

SHEILA B. BLUME, M.D.

on behalf of the

NATIONAL COUNCIL ON ALCOHOLISM, INC.

and the

AMERICAN MEDICAL SOCIETY ON ALCOHOLISM

before the

SUBCOMMITTEE ON ALCOHOLISM AND DRUG ABUSE
U.S. SENATE

"The Effects of Alcohol Consumption During Pregnancy"

September 21, 1982

Testimony U.S. Senate Subcomittee on Alcoholism and Drug Abuse
September 21, 1982

Good morning, I am Sheila Blume, director of the NYS Division of Alcoholism and Alcohol Abuse, and a physician with 20 years of experience in the treatment of alcohol problems. As State director I headed a Governor's Task Force on FAS in 1979 and have directed a statewide education campaign which followed its recommendations. I am delighted to be here today to speak, not as a state official, but as a volunteer, a member of the Board of Directors of the National Council on Alcoholism and immediate past president of the American Medical Society on Alcoholism, on behalf of those two organizations.

NCA is the only national voluntary organization founded to combat the disease alcoholism. It has over two hundred Affiliates around the country which for almost 40 years have engaged in public education, advocacy, information and referral activities.

AMSA is an organization of more than 1000 physicians in the United States and Canada, devoted to promoting professional education and adequate programs of prevention and treatment for alcoholism.

We are here today to discuss a problem of unquestioned importance. NCA recognized the public health implications of the early research on alcohol-related birth defects and took an active role in stimulating research and disseminating the knowledge gained. In 1971 NCA convened the first conference at which fetal alcohol effects were described to scientists in the United States. Shortly afterward NCA awarded grants to support further research in this country. The Research Society on Alcoholism, an NCA Component at that time, convened an FAS study group which still meets for researchers to share their information.

Reports of research already completed and preliminary data from studies in progress, both human and animal, clearly establish the teratogenic effects of alcohol. Of course, much more needs to be learned, particularly concerning:

- more subtle fetal alcohol effects which may not be obvious at birth, including possible interference with learning, behavior or personality development
- mechanism(s) of damage
- protective factors
- quantity of alconol and timing of intake necessary to produce various harmful effects
- individual differences in susceptibility to alcohol-related damage
- safe levels of alcohol intake (if any) during pregnancy
- possible effects of paternal alcohol use on offspring.

NCA and AMSA strongly support continued federal funding for special research and President Reagan's request to increase federal alcoholism research by over 50% in 1983. However, armed with the information currently available, we have before us an unparalleled opportunity for prevention according to NIAAA's 3rd Special Report on Alcohol and Health. Fetal alcohol syndrome is now considered the 3rd most common cause of mental retardation associated with birth defects in the United States, and the only one of the three which is entirely preventable. In New York State, for example, our task force estimated that the infants affected by alcohol-related birth defects born in one year alone (1978) would require a sum of $155,000,000 in additional lifetime care.

In order to accomplish this preventive task we must reach two important groups of women of childbearing age: those who are free of alcohol problems and can refrain from drinking during pregnancy in response to information on the effects of alcohol, and those who are suffering from alcoholism or are alcohol abusers. A sub-group which needs special attention is teenage girls. There are over 1.1 million teen pregnancies a year. Among high school girls, according to a 1978 Research Triangle Institute Study, 9% of high school girls were classified as heavy drinkers, that is, they drank 5 or more drinks per occasion at least once a week. Taken together, these statistics begin to define a considerable population risk.

Both women who drink without problems and those who are alcoholic need information about risks to the fetus of drinking during pregnancy. The latter group of women, however, will also require help in identifying their alcohol problems and will require treatment to overcome them. To reach both of these groups, the following components will be required as a minimum.

1. public education - in the form of special campaigns, by incorporation into ongoing health education curricula, and through warning labels on alcoholic beverages
2. professional education - for all health professionals, but particularly those in obstetrics, pediatrics and family and community health
3. simple, practical and effective systems for the routine screening, identification and referral of problem drinkers in all obstetric practices (Such systems should also be available prior to pregnancy in premarital exams or family planning settings).
4. effective and accessible treatment services for alcoholic women and their families, which can take advantage of the desire of the pregnant

woman to bear a healthy child to aid in motivation for alcoholism treatment

5. effective identification and treatment services for those infants and children suffering from fetal alcohol effects.

I would like to comment on the first three components.

1. Public education. There are a number of effective approaches to public information. The Surgeon General's Advisory, warning women not to drink if they are pregnant or considering pregnancy, was one of the most important initiatives in public education and one which NCA both approves and applauds. Major efforts have been made by private and voluntary organizations such as the alcoholic beverage industry, and the March of Dimes. Another example is the Will Rogers Institute, which, in cooperation with New York State, produced a public service message on alcohol and pregnancy, starring Rita Moreno, which was shown on television and distributed to theaters all over the country, both in English and Spanish. NCA's 220 affiliates have been major participants in these public information campaigns, and NCA has begun its own FAS training for teenage girls. The federal government (NIAAA and BATF) have produced and distributed material, and a number of states have undertaken campaigns, usually in cooperation with the voluntary sector. I have appended to this testimony a sample of New York's professional and public information materials, which we make available at cost to other states. Radio and television messages, posters and pamphlets are supplemented by a series of educational presentations at the regional and county level organized by local governments, councils on alcoholism and other

voluntary agencies. This program is now being evaluated, in a survey of 500 New York obstetricians-gynecologists conducted by Dr. Marcia Russell of the Research Institute on Alcoholism in Buffalo. This study assesses the awareness of these physicians of FAS, their practices in evaluating and advising women on alcohol use in pregnancy, their frequency of diagnosis of referral for alcoholism treatment and their reactions to the state's professional education campaign. I will gladly provide a copy of this report when it is completed.

NCA and AMSA agree that the most effective public message will be one which is direct and accurate; and which neither exaggerates nor downplays the risk of damage. By direct, we mean directly stating the fact that alcohol can be toxic to the fetus. Messages that simply say "ask your doctor" are not sufficient because many women do not receive adequate medical care, and do not seek such care early in pregnancy, for economic or other reasons. A significant number of these women and girls (for many are teen-agers) are at high risk. I have attached to the written testimony an article from the January 1981 edition of the U.S. Journal of Drug and Alcohol Dependence analyzing a number of these messages. We strongly recommend that the federal government not give up its public education initiatives.

NCA and AMSA also strongly recommend federal action to require health warning labels on beverage alcohol containers. Policy statements of both organizations on this subject are attached. Public information campaigns, by their very nature, are time-limited.

The warning label is one way to assure that the danger of alcohol to the fetus becomes part of the accepted general knowledge -as well known to every member of our society as the knowledge that overeating will cause a gain in weight.

2. Professional education. AMSA and NCA have long been concerned about improving professional education. Not only is there a need for ducation concerning the teratogenic effects of alcohol. More importantly, training in the skills necessary to identify alcoholism and to intervene effectively is critical in preventing FAS, as I have mentioned. Information alone will not help a woman suffering from alcoholism.

   The federal government can help by continuing to support both needed research and the means for its dissemination such as professional conferences and information services. Direct programs, such as the support of alcoholism teaching in family practice departments of medical schools, and particularly the career teachers program, have made an enormous difference in medical education. We appeal for the continuation of that excellent effort.

3. Practical systems for identifying alcohol problems in obstetrical practices. It should be part of the routine health care of every American woman, and most especially the woman receiving obstetric care, that a careful history be taken of her alcohol intake, and that any alcohol related problems be investigated. Women known or suspected to be problem drinkers should be routinely and adequately referred for treatment, and followed up to make sure they receive it. Unfortunately, it is my experience that this is not the case today,

in spite of the fact that, for example, an obstetrical clinic in Buffalo, NY, found an incidence of 3%, one out of 33 women coming in for care, reporting drinking an average of 6 drinks or more per day, putting them at high risk for FAS. An additional 4% reported having six or more drinks per day on days when they drank.

Alcohol problem identification today rests primarily with individual practitioners, most of whom are not adequately trained for this task. The previously-mentioned survey by Dr. Russell found that 40% of the obstetricians-gynecologists polled referred no patients for treatment of drinking problems during the past year. There is an urgent need to develop simple, practical workable systems which can be adapted to different obstetric settings, and to develop strategies to stimulate their adoption nationwide. Various models of such systems have already been developed but are not widely used. We recommend that the Surgeon General, with the cooperation of the Congress, convene a task force made up of recognized leaders in the fields of obstetrics, pediatrics, public health, family medicine, psychiatry and alcoholism, and representatives of the American Medical Association the American Nurses' Association and the American Hospital Association, to review present efforts, recommend workable practical systems, and, most important, develop a strategy to promote implementation of such a system in every community in the nation. We believe that only the federal government has the breadth and scope of public health responsibility to undertake such an effort and make it work. This is an opportunity for the federal government to bring together the private and public sectors, to achieve what no one organization, state, or medical specialty can possibly accomplish. Of course, we at NCA and AMSA stand ready to help in such an undertaking in any way possible.

Today we are faced with a unique opportunity to achieve prevention of human suffering and disability, but a great deal of work remains to be done before that can be accomplished. I hope you will seriously consider our recommendations and that you will take us up on our offer of help.

NCA Reports

NATIONAL COUNCIL ON ALCOHOLISM, INC. • 733 THIRD AVENUE, NEW YORK, N.Y., 10017 • (212) 986-4433

POSITION STATEMENT ON FETAL ALCOHOL SYNDROME

Observations of human babies and of experimentally treated animals have made it clear that a mother's heavy drinking may severely damage her unborn child. We do not know the exact amount or timing of drinking that causes these effects. We cannot say whether there is a safe amount of drinking or whether there is a safe time during pregnancy. We do know that heavy drinking may be damaging. Women should therefore be especially cautious about drinking during pregnancy and when they are likely to be pregnant. However, because of the possibility of risk, and in order to be totally safe, a woman should not drink at all during her pregnancy.

Research is proceeding vigorously in this area. NCA supports and encourages this important research and urges both public and private agencies to continue their support of research on the effects of alcohol on the fetus.

PASSED

2/1/80	Public Policy Committee
5/4/80	AMSA Executive Committee
5/6/80	RSA Executive Committee
6/13/80	NCA Executive Committee

POSITION STATEMENTS & RESOLUTIONS

NCA Reports

NATIONAL COUNCIL ON ALCOHOLISM, INC. • 733 THIRD AVENUE, NEW YORK, N.Y., 10017 • (212) 986-4433

AMSA POSITION ON LABELING

The American Medical Society on Alcoholism firmly defends the public's right to know, and supports the adoption of all effective methods of public education on the potential dangers associated with the excessive use of alcohol, to encourage informed decision making by the public, and to reduce the incidence of alcohol-related problems. Although suitable scientific study is not now available to prove in advance the effectiveness of warning labels on alcoholic beverages, the American Medical Society on Alcoholism, as expressed in a poll of its membership, believes that warning labels on alcoholic beverages has sufficient potential utility to warrant its adoption. Such adoption should be accompanied by carefully designed and adequately funded studies of the effectiveness of this program in improving public awareness of the hazards of excessive alcohol use.

The American Medical Society on Alcoholism further recommends that any system of labeling adopted be applied to all alcoholic beverages and alcoholic beverage advertising, that the message include both specific and general information and that all alcoholic beverages be labelled to indicate their alcohol content in volume percent.

PASSED

10/18/79 AMSA Executive Committee
10/19/79 NCA Public Policy Committee
10/20/79 NCA Board of Directors

NCA POSITION ON LABELLING

Because of the overwhelming evidence that the consumption of alcohol can lead to serious health problems, including birth defects, alcoholism and cancer, and because it believes in the public's right to know, the National Council on Alcoholism supports requiring specific health and safety warning labels as well as information on ingredients, calories and alcohol content by volume on alcoholic beverage containers.

Specific warnings on alcoholic beverage containers should be part of a rotating series of notices and address such areas as: the illegality of driving under the influence of alcohol, selling alcoholic beverages to minors, cirrhosis, cancer, FAS, alcohol and drug interactions.

National Council on Alcoholism, Inc.
731 THIRD AVENUE, NEW YORK, N.Y. 10017 • (212) 986 4433

June 3, 1977

MEMORANDUM

TO: NCA Member Organizations

FROM: Frank A. Seixas, M.D., Medical Director

SUBJECT: To assist in responding to inquiries about the Fetal Alcohol Syndrome

On May 31, 1977 there was a very successful press conference at which NCA announced the awarding of a grant on the fetal alcohol syndrome and its interest in alerting obstetricians, other physicians, and the women of America to the hazards of drinking during pregnancy.

We can say with confidence that women who are alcoholic and who are drinking heavily during pregnancy have a very high risk of giving birth to a baby who has some deformity and/or mental deficiency. Whereas we know this for sure, we do not know how small an amount of alcohol might slightly increase the chances for abnormalities in the offspring. Research on this area of investigation is now going on. Because of the possibility of a risk, we have come out with the idea that in order to really be safe a woman might not drink at all during her pregnancy. However, in no sense are we saying that there is a significant chance of fetal deformity with small doses of alcohol. Even for women who have been drinking heavily during their pregnancy, there is already some evidence that whenever they stop, they improve their chances of decreasing the seriousness of fetal alcohol effects.

NCA is supporting research on exploring how "social drinking" and binge drinking might affect the fetus. When this is known we may have more definite conclusions about how much it would be permissible to drink while pregnant.

Senator **Humphrey**. Thank you, Dr. Blume.

Dr. Bissell, welcome back.

Dr. **Bissell**. Thank you. Mr. Chairman, I am an internist from New York and a member of the AMA's panel on alcoholism. This hearing is particularly timely for us now because the AMA house of delegates adopted a major report entitled "Fetal Effects of Maternal Alcohol Use" just in June of this year, and you have a copy of that.

The report discusses current research in this area and makes several recommendations regarding needed research and dissemination of information to the public. The report will also be published in JAMA, the Journal of the American Medical Association, later this year.

Research clearly indicates that excessive use of alcohol during pregnancy can negatively affect the fetus. Alcohol present in the mother's bloodstream readily enters the circulation of the fetus and approximately 1 in 750 infants born in the general population are born with serious physical defects that collectively are described as fetal alcohol syndrome. This is comparable to the incidence of spina bifida and Down's syndrome; 30 to 40 percent of the infants of alcoholic mothers suffer from some form of fetal alcohol syndrome.

These effects may include facial deformity, prenatal and postnatal growth deficiencies and involvement of the nervous system with mild to serious mental retardation. An increased incidence of other serious birth defects is also noted.

In addition to the effects of maternal alcohol use observed in living newborns, there appears to be an increased incidence of stillbirths and spontaneous abortions among women who have three or more drinks per day during pregnancy.

Thus, the report finds that the evidence is clear that a woman who drinks heavily during pregnancy places her unborn child at substantial risk for fetal damage and physical and mental deficiencies in infancy.

Some of the research to date suggests that even moderate use of alcohol during pregnancy may affect the fetus. However, this work is not conclusive. For example, conflicting evidence exists on the effects of moderate drinking on premature delivery, decreased birth weight and decreased placental weight.

More convincing, although still inconclusive, is evidence associating moderate drinking with spontaneous abortion, behavioral dysfunction, adverse mental and motor development, and impaired newborn conditioning. More research is needed on the effects of moderate alcohol use on these and other potential effects.

Three problems exist in analyzing the research on effects of maternal alcohol use. First, most studies are based upon self reports of drinking, and consequently accuracy cannot be verified.

Second, most refer to average daily intake, therefore providing no insight into the difference between a constant level of consumption and binge drinking. Third, there is no uniform definition of what moderate drinking is. These problems increase the uncertainty regarding the level of alcohol consumption that creates risk to the fetus.

In addition to the need to determine if a safe level exists, and if so what it is, the AMA has identified several areas that need additional research. Current research does not adequately address the duration of the known effects on infants. Research is needed to determine whether, over a period of time, those infants suffering growth deficiencies at birth will reach average size.

Likewise, whether the intelligence of an infant who is mentally retarded at birth may improve as the child grows is an area that needs further research. Also, more is needed in the area of subtler or delayed adverse effects. The current research focuses on effects apparent at birth Areas that need to be further researched include influence of other variables, such as bad nutrition, drugs and poverty, drinking patterns and behavior, differences in beverages and paternal alcohol use.

The lack of conclusive research regarding moderate use of alcohol during pregnancy presents a problem of what advice physicians should be giving to pregnant women and women planning to conceive. In our view, until a definitive determination of risk is made, physicians should inform their patients as to what the research to date does and does not show, and encourage them to decide about drinking in light of the evidence and their own situations.

Physicians should be explicit in reinforcing the concept that even with several aspects of the issue still in doubt, in view of the possibility of serious damage to the brain and body of the unborn, the safest course is abstinence. This policy was adopted by the AMA house of delegates in June of this year.

While there are those who question the wisdom of raising the issue of potential effects of moderate alcohol use with pregnant women in the absence of definitive evidence clearly establishing the hazard, the AMA believes that the current research raises a sufficient possibility of risk to warrant informing the pregnant woman. Once the pregnant woman is aware of the potential risks of even moderate alcohol use, she can determine the appropriate course for her. Further research will resolve the issue of whether it is possible to establish a safe level of alcohol consumption during pregnancy.

Mr. Chairman, Dr. Takamine, who is chairman of the AMA's panel on alcoholism of the council of scientific affairs, will continue our statement.

Senator HUMPHREY. Thank you.

Dr. TAKAMINE. Mr. Chairman, I am Joe Takamine, a practicing internist from West Los Angeles. I thank you for this opportunity again to appear before you.

To try and summarize briefly the material in our complete statement, the AMA has focused its educational efforts toward the public and toward the medical profession and allied health personnel.

With regard to the public, there have been meetings with government officials, voluntary organizations, schools, churches—almost any organization willing to sit down and share their interest and their concern about the problems relating to drinking, not just to fetal alcohol syndrome, Mr. Chairman.

Because of the increasing interest that is being evoked and that the public is showing, the AMA is now in the process of preparing a booklet which will be issued to the general public. This is not a scientific or highly technical booklet for the medical profession.

Another method or means of disseminating information or informing is labeling. As you remember, back in 1979 we testified before the subcommittee on that issue. The AMA at that time supported legislation with regard to alcohol labeling, and supports it at this time. The label we put forth at that time was a very simple label which went, "Alcohol may be injurious to your health and, if consumed during pregnancy, to the health of unborn children." As I say, Mr. Chairman, the AMA still supports that position.

With regard to informing and educating the medical profession and allied health personnel, the *JAMA*, as you heard earlier from Dr. Brandt, has published an article. There have been countless meetings and seminars. We have tried to get material pertinent to alcohol use, misuse and abuse into regional meetings of all the various disciplines involved in medical care and in allied health care and with the nurses also. This goes on constantly.

And if I may interject a note, Mr. Chairman, that is not in the written testimony, one of the difficulties that everybody has found in this field who deal with this problem to which you are addressing this meeting today, and the entire issue of alcoholism and alcohol-related problems, is that matter of transforming information to which Dr. Blume talked a few minutes ago into educational material. There is a barrier in between that; namely, the attitude of the people who are going to receive this information and what it means to them in a heterogeneous population like this country.

This has just presented tremendous obstacles, as you know, toward first getting the information out to these groups and then having actually the educational process take place so the people will change their attitudes; that is, look at alcohol as a toxin, and the things that you were talking to Dr. Brandt and Dr. Mayer about.

With regard to the medical profession, this is no simpler a matter than it is to the general public, as you are well aware. Meetings, seminars and symposia go on. In the medical schools over the last several years, changes have taken place, and now, in approximately 91 percent of the medical schools, courses on alcohol, alcoholism and alcohol-related problems were offered as a more cohesive entity than with just the teaching of the pathology of alcoholism which went on in the medical schools when several of us were in medical school. And there is more than just an academic interest.

At a symposium 2 years ago on moderate drinking, which I chaired in San Antonio, the subject which far and away garnered the greatest interest and concern was a presentation by a person well known to this panel on the fetal alcohol syndrome. It was the first time many of us had heard this matter presented at a formal AMA meeting.

But I can tell you not only from the panel's point of view, Mr. Chairman, but from the audience, the speaker on fetal alcohol syndrome was the last speaker and they all stayed through a 3-hour meeting and 95 percent of the questions at the end of the entire symposium were directed toward this one subject—obviously for a multitude of reasons which I cannot enumerate. But the interest at that time was strongly evident.

In conclusion, Mr. Chairman, the research to date indicates that we should be concerned about any level of drinking during pregnancy. The research is by no means conclusive, but until more research is available to resolve the issues definitively, we believe the only safe course is to abstain from drinking during pregnancy.

Whereas we encourage the research in the laboratories, when you are a practicing physician, what you have to deal with obviously is the patient on the other side of the desk and what may eventuate from that pregnancy.

The AMA supports the concept of physicians conveying this information to patients. Therefore, the AMA believes physicians' knowledge must be increased, and this can be and will be accomplished through medical publications, medical education and meetings. In addition, extensive public educational efforts should be conducted. One important component of this effort—and you have heard this from the previous people—should be to reach women, particularly the teenagers, prior to consulting a physician.

We want to assure you that the AMA has been involved and supportive of these educational efforts in the past and is committed to so doing in the future.

Again, Mr. Chairman, thank you for this opportunity to come before you. Thank you, sir.

[The joint prepared statement of Dr. Bissell and Dr. Takamine follows:]

STATEMENT
of the
AMERICAN MEDICAL ASSOCIATION
to the
Subcommittee on Alcohol and Drug Abuse
Committee on Labor and Human Resources
United States Senate

RE: Fetal Effects of Maternal Alcohol Use

Presented by: LeClair Bissell, M.D.
Jokichi Takamine, M.D.

September 21, 1982

Mr. Chairman and Members of the Committee:

My name is LeClair Bissell, M.D. I am a physician in the practice of Internal Medicine in New York City and serve as a member of AMA's Panel on Alcoholism. Joining me today is Jokichi Takamine, M.D., a practicing internist from Los Angeles, California and also a member of AMA's Panel on Alcoholism. Accompanying us is Ross Rubin, Director of AMA's Department of Federal Legislation.

The AMA appreciates the opportunity to present its views on the fetal effects of maternal alcohol use. This hearing is particularly timely for us since the AMA House of Delegates adopted a major report entitled "Fetal Effects of Maternal Alcohol Use" in June of this year. (Attached) This report discusses current research in this area and makes several recommendations regarding needed research and dissemination of information to the public.

Effects of Maternal Use of Alcohol

Research clearly indicates that excessive use of alcohol during pregnancy can negatively affect the fetus. Alcohol present in the mother's blood stream readily enters the circulation of the fetus. Approximately 1 in 750 infants born in the general population are born with serious physical defects that collectively are described as fetal alcohol syndrome. This is comparable to the incidence of spina bifida and Down's syndrome. Thirty to forty percent of infants of alcoholic mothers suffer from fetal alcohol syndrome. The effects of fetal alcohol syndrome include facial disfiguration, pre-natal and post-natal growth deficiencies and involvement of the nervous system with mild to moderate mental retardation. An increased incidence of other serious birth defects is also noted. In addition to the effects of maternal alcohol use observed in living newborns, there appears to be an increased incidence of stillbirths and spontaneous abortions among women who have three or more drinks per day during pregnancy. Thus, the report finds that "the evidence is clear that a woman who drinks heavily during pregnancy places her unborn child at substantial risk for fetal damage and physical and mental deficiencies in infancy."

Some of the research to date suggests that even moderate use of alcohol during pregnancy may affect the fetus. However, this work is not conclusive. For example, conflicting evidence exists on the effects of moderate drinking on premature delivery, decreased birth weight and decreased placental weight. More convincing, although still inconclusive, is evidence associating moderate drinking with spontaneous abortions, behavioral dysfunction, adverse mental and motor development and impaired newborn conditioning. More research is needed on the effects of moderate alcohol use on these and other potential effects.

Three problems exist in analyzing the research on effects of maternal alcohol use. First, most studies are based upon self-reports of drinking, and consequently accuracy cannot be verified. Second, most refer to average daily intake, therefore providing no insight into the difference between a constant level of consumption and binge drinking. Third, there is no uniform definition of moderate drinking. These problems increase the uncertainty regarding the level of alcohol consumption that creates risks to the fetus.

In addition to the need to determine if a safe level exists, and if so what it is, the AMA has identified several areas that need additional research. Current research does not adequately address the duration of the known effects on infants. Research is needed to determine whether over a period of time those infants suffering growth deficiencies at birth will reach average size. Likewise, whether the intelligence of an infant who is mentally retarded at birth may improve as the child grows is an area that needs research. Also, more research is needed in the area of subtler or delayed adverse effects. The current research focuses on effects apparent at birth. Areas that should be further researched include influence of other variables such as poor nutrition, drugs and poverty, drinking patterns and behavior, differentials in beverages, and paternal alcohol use.

Physician Activity

The lack of conclusive research regarding moderate use of alcohol during pregnancy presents a major problem of what advice physicians should be giving to pregnant women and women planning to conceive. In our view, until a definitive determination of risk is made, physicians should inform their patients as to what the research to date does and does not show, and to encourage them to decide about drinking in light of the evidence and their own situations. Physicians should be explicit in reinforcing the concept that, even with several aspects of the issue still in doubt, in view of the possibility of serious damage to the brain and body of the unborn the safest course is abstinence. This policy was adopted by the AMA House of Delegates in June of this year. While there are those who question the wisdom of raising the issue of potential effects of moderate alcohol use with pregnant women in the absence of definitive evidence clearly establishing the hazard, the AMA believes that the current research raises a sufficient possibility of risk to warrant informing the pregnant woman. Once the pregnant woman is aware of the potential risks of even moderate alcohol use, she can determine the appropriate course for her. Further research will resolve the issue of whether it is possible to establish a safe level of alcohol consumption during pregnancy.

Mr. Chairman, Dr. Takamine will now continue our statement.

Education

Methods of disseminating the knowledge available on fetal alcohol effects must be addressed to two groups - physicians and the public. Physicians have the opportunity to advise their patients of the potential risks to the fetus. However, this is not a complete solution since many women will not seek advice from a physician until after they are pregnant. This is particularly true of disadvantaged women and teenage girls. If a physician is not consulted prior to conception, harm to the fetus may occur prior to the initial contact with a physician. Therefore, efforts to inform the public about the fetal effects of alcohol are extremely important.

The Association strongly supports public education efforts. Some governmental agencies and professional associations are involved in programs to increase public awareness on fetal effects of alcohol. The AMA believes the effectiveness of these efforts would be increased by involvement of schools, hospitals and community organizations. The Association is preparing a booklet on this topic that will be available for use by the public. We believe this booklet will be useful to many organizations in conducting their public education efforts.

Another method of disseminating information, also supported by AMA, is through the label on alcohol bottles. In 1978, the AMA House of Delegates recommended that warning labels on alcohol containers should provide the following warning "Alcohol may be injurious to your health and, if consumed during pregnancy, to the health of unborn children". The Association testified in support of alcohol labeling legislation in 1979.

In addition to educating the public, there is continuing need to educate physicians. The American Medical Association and other medical groups are active in this effort. Medical publications, such as the *Journal of the American Medical Association*, are used to provide physicians with the latest medical information. The *Journal of the American Medical Association* has published articles on the research relating to the fetal effects of maternal alcohol use. In 1978, *AM News*, a newspaper for physicians published by the AMA and distributed to all members, contained a letter, endorsed by AMA and the American College of Obstetricians and Gynecologists, which discussed the fetal effects of alcohol. The letter endorsed the principle of physicians' distributing patient information on fetal alcohol syndrome. In New York, a public education program built on the message "that to be perfectly safe, women should abstain from alcohol during pregnancy," was conducted in conjunction with a professional education effort. The New York State Medical Society assisted in this effort by preparing a questionnaire for physicians to use with pregnant women to determine the extent of their alcohol and tobacco use. These efforts by the profession need to be and will be continued.

Medical education, both initial training and continuing education for the practicing physician, is used to provide information on new research. The AMA does not prescribe the content of medical school curriculum but we do encourage emphasis on appropriate subjects, such as alcohol abuse and related topics. The number of medical schools that have specific courses on alcoholism is increasing. Currently, 91 medical schools have such courses. Information on fetal effects of maternal alcohol use is included in such courses. This information is also presented in obstetrics courses.

Meetings of medical groups can also be used to convey information to practicing physicians. For example, at the AMA's 33rd Winter Scientific Meeting in 1980 a "Symposium on Moderate Drinking" was held. This provided the opportunity for physicians attending the meeting to learn about the latest research in the area of moderate drinking and effects on the fetus.

Conclusion

Mr. Chairman, the research to date indicates that we should be concerned about moderate drinking during pregnancy. The research is by no means conclusive, but, until more research is available to resolve the issue definitively, we believe the only safe course is to abstain from drinking during pregnancy.

The AMA supports the concept of physicians' conveying this information to patients. Therefore, the AMA believes physicians' knowledge must be increased. This can be accomplished through medical publications, medical education and meetings.

In addition, extensive public education efforts should be conducted. One important component of this effort should be to reach women prior to their consulting a physician.

We want to assure you that the AMA has been involved and supportive of these education efforts in the past and we are committed to doing so in the future.

In this regard, we want to commend this Committee for its interest in this area and for continuing to highlight this important subject with today's hearing.

Mr. Chairman, at this time, we will be pleased to answer any questions the Committee may have.

Senator HUMPHREY. Thank you both.

Dr. Little?

Dr. LITTLE. Thank you, Mr. Chairman. It is a pleasure to be here and to discuss with you the subject of alcohol consumption during pregnancy.

I think the risks have been eloquently documented by Dr. Brandt and members of this panel, many of whom I have the pleasure of working with, so I will not review those. Rather, I will say that I have had the privilege of working at the University of Washington with the team that first identified fetal alcohol syndrome in this country 10 years ago. We have been at it ever since.

I believe I can speak for my colleagues, too, that we are in agreement with Dr. Brandt's testimony. There is a spectrum of fetal alcohol effects. They range from mild to fatal. We know of no safe level of alcohol use. More research is needed on that. We know of no safe time period, we know of no safe beverage, and we know of no person who bears a child who is not vulnerable at some level to drinking.

So, with that statement, I must say also that we agree with the advisory issued by the Surgeon General and the statement by the American Medical Association that the safest course of action for pregnant women is abstinence.

I would like to stress, however, that we believe this is easier than it sounds, because women appear to have a natural aversion to alcohol during pregnancy. When I first began to work in this field before fetal alcohol syndrome was identified, I was amazed to hear women say things to me such as, "Well, I knew I was pregnant because I refused my favorite drink." So, I think when we ask women to abstain, we are not asking as much as we think, and it is a reasonable request.

For most of my testimony, though, I would like to tell you about something that we have done in Seattle, Wash., that addresses what we are talking about here today, which is the dissemination of information, the training of professionals, and the help that we need to give to women and their children.

I think Dr. Blume has summed up beautifully what we need to do, and Dr. Fabro has talked about the role of the obstetrician. My colleagues from the American Medical Association have made crystal clear the importance of the problem.

We have tried to do something about it, and I must say it has been the most difficult experience I have ever had. To do research is trivial compared to trying to do something about a problem.

We got in this business 5 years ago because since fetal alcohol syndrome was identified in this country in Seattle and we were very active in the field, we had the privilege of talking with many, many women who had had children and drunk heavily. We also saw their children.

Instead of being able to pursue our research and be calm, cool, and collected, we found ourselves getting involved with the human beings. We found women saying, "If I had only known," and we found ourselves looking at children who were irretrievably damaged needlessly. It seemed like someone ought to do something.

I am research-trained and that is where my primary interest lies. My colleagues were also research-trained. They were clinicians, too, but their primary interest and what they were paid to do was research. In spite of that, it seemed that somebody had to do something, so we tried. And we were fortunate to receive from the National Institute on Alcohol Abuse and Alcoholism a sum of money to try ways of preventing fetal alcohol effects in King County, Wash. That project lasted for 3 years. We are trying to evaluate how successful we were.

I would like to tell you very briefly the basic things that we did and what I know about how they came out. As Dr. Blume pointed out, we felt that we needed to get information to the public. We needed to reach the professionals who saw the pregnant women and their children after they were born, and we needed to give some help to the women, both during pregnancy and after, and to their children. So, those were the three ways in which we wanted to get the message out in King County.

Now, remember, this is the birthplace of FAS in this country. So, of course, public——

Senator HUMPHREY. We will not forget.

Dr. LITTLE. Excuse me?

Senator HUMPHREY. We will not forget.

Dr. LITTLE. OK, thank you. [Laughter.]

Public awareness should have been very high, but, in fact, when we went out to look, 92 percent of our population was aware of the risk, but they did not know how much they could safely drink if they were pregnant.

About 16 percent said, "Well, maybe women should be abstinent." But among the balance, the average that they thought pregnant women could drink safely was three drinks a day, and among younger people it was four and five drinks a day, which was very alarming to us.

Also, we found that one-third of the obstetricians in King County were not addressing alcohol use at all, in spite of all the publicity that we had had in that area. We also found that there was nowhere for a pregnant woman who had an alcohol problem to go where both the alcohol problem and the pregnancy could be cared for together.

The obstetricians were appalled by the alcohol problem. The alcohol counselors were appalled by the pregnancy. This was a sorry state of affairs for a place that calls itself the birthplace of the fetal alcohol syndrome in this country, and yet it was the case when we began in 1978.

I can tell you that 3 years later, the results are far from complete, but some progress has been made. Much of this has been with the help of the Federal Government, not only by our grant funds but by the Federal effort through the NIAAA that Dr. Brandt described.

I can tell you that we got a simple message to at least 1 million residents in our target area. The message was simple; it stressed abstinence. That was very controversial at the time, but it was what we chose to do. We can tell you, too, that now, 3 years after we began, the number of women abstaining at the first prenatal visit has doubled.

What we are sorry to tell you is that women do not seem to have changed their drinking patterns around the time of conception.

And, Mr. Chairman, as you pointed out very correctly, what happens very early in the pregnancy, and perhaps even prepregnancy, is of great concern to us. That does not seem to have changed.

We can tell you that we have reached 13,000 professionals who see the woman or her child, and that obstetricians almost universally now, by our second survey, are addressing alcohol use during pregnancy, and most of them are recommending abstinence or, at most, two drinks a day as a maximum.

We can also tell you that we have set up a crisis service, an information line, so that women who were concerned about this simple public education message could call and get support and more information, and I think it is crucial. Dr. Blume has recommended simple systems; I think that is a simple system that will work, and it can be staffed by volunteers. Our information line was used by 1 in every 40 pregnant women in King County.

I can also tell you that we saw 655 pregnant women, their children, and their families in 2 years of active operation. We believe that we saw 15 percent of all the alcohol abusers in King County who were pregnant in the period.

So, it can be done; it is not terribly expensive. The entire cost of the program was less than what it would cost if we had had three fetal alcohol syndrome children born in our area.

I think we know a lot about drinking during pregnancy. My personal opinion is that it is time to move on. There are exciting and urgent areas where we should be doing research. There are other facets of reproduction besides pregnancy. For example, it is time to look at the father, as you pointed out. The father may play a role, and we do not know how. Also in lactation, alcohol enters the mother's milk, and some of the damage that we ascribe to pregnancy may, in fact, be due to maternal drinking during lactation. If so, we need to know.

But I think most important is our need to know how to prevent these preventable effects. There are two kinds of women, as Dr. Blume has pointed out. One of them has a choice, and she will hear our simple messages and she will respond to her obstetrician and other health care professionals and say, "It does not taste very good anyway; I do not think I will drink."

We need to know how to reach that woman, but even more important, we have to reach the woman who has lost the choice of how to act on that information. We do not know how to do that well. I think that is the important question that we must address: how to find that woman, how to reach her, and how to treat her. These fetal alcohol effects are preventable and we need to know how to do it now. Thank you.

[The prepared statement of Dr. Little follows:]

Testimony of

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FETAL ALCOHOL EFFECTS AND THEIR PREVENTION

before the
Subcommittee on Alcoholism and Drug Abuse
Committee on Labor and Human Resources
United States Senate

September 21, 1982

Mr. Chairman, members of the Subcommittee, I am happy to be here today and to discuss with you the important issue of the risks of drinking during pregnancy.

Nearly ten years has passed since publication of the landmark report linking alcohol use by pregnant women to birth defects in their children.(1) In that report, University of Washington physicians and scientists described what is now called the "fetal alcohol syndrome", one of the most serious consequences of alcohol use during pregnancy. Hundreds of cases of the syndrome have now been reported throughout the world, and there is no longer any doubt that alcohol use during pregnancy can seriously damage the fetus.

In the last ten years, we have learned that there is a much broader spectrum of possible adverse consequences for the child linked to maternal alcohol use during pregnancy. These consequences are termed "fetal alcohol effects", and they range from mild to fatal. The fetal alcohol syndrome is a dramatic example of the severe end of the spectrum. As yet, no one can say with certainty how much drinking will result in a particular fetal effect, or why some babies are damaged by alcohol and some are not. One can only say that known risks exist, that they are serious, and that the resultant economic, social, and personal costs are high. In my testimony today, I will review these risks of drinking during pregnancy and the magnitude of the problem they represent. Ways in which fetal alcohol effects may be prevented will then be suggested, based on our clinical experience in King County, Washington.

FETAL ALCOHOL EFFECTS[a]

HOW ALCOHOL AFFECTS THE DEVELOPING FETUS

There are four principal ways in which alcohol use during pregnancy affects the developing child. These are:

- Growth retardation
- Abnormal physical development
- Central nervous system dysfunction
- Fetal and perinatal death

These problems demonstrate the broad spectrum of fetal effects that have been described when women drink during pregnancy. Not only do the effects vary in type, but they vary in severity. When the first three effects appear concurrently and in severe form, they are diagnostic of fetal alcohol syndrome (FAS). The FAS child is usually seriously impaired. There is extreme growth retardation, unusual facial morphology, and mental retardation. There is also a probability of malformations in various other organ systems. This damage is permanent, and the child will not catch up in growth or intelligence. One or two children in every 1,000 born have fetal alcohol syndrome. FAS is one of the three most common birth defects in the United States, and the only one that is now preventable.

But FAS is only an extreme manifestation in the spectrum of fetal alcohol effects linked to maternal drinking. Growth retardation, physical abnormalities, and central nervous system (CNS) dysfunction can occur independently of each other. They may also vary in severity from insignificant to profound. Each of these fetal alcohol effects will be described briefly.

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[a] For clarity of presentation, references are cited only when specific studies or findings are mentioned. Documentation for the more general statements in this testimony can be found in the several excellent research reviews listed under Supporting Literature. An Appendix is also attached to explain the basis for calculation of selected estimates presented here.

Growth Retardation

The FAS child is extremely small at birth, generally in the lowest three percent of all newborns for length, weight, and head circumference. But other infants of alcohol abusers who do not have FAS are generally small, too. In one study, 50 newborns whose mothers were alcohol abusers were more than a pound lighter, on the average, than newborns of infrequent drinkers.(2) Some, but not all, studies of "social drinkers" also report small decreases in the birthweight of their children. The growth retardation seen in infants of drinking mothers is not necessarily due to prematurity, since this variable is usually taken into account. The probability that alcohol itself is responsible for the growth retardation is strengthened by the fact that babies weigh more when heavy drinking mothers reduce their consumption, even as late as the third trimester.

Physical Abormalities

Physical abnormalities that have been linked to alcohol use during pregnancy include the cluster of facial abnormalities that characterizes the FAS child, and that is responsible for his/her distinctive appearance. These are thought by some to be a reflection of inadequate brain development. In addition, abnormalities of various systems appear with much higher frequency than expected: cardiac, urogenital, and skeletal malformations are frequently reported. In general, children of alcohol abusers show an increased frequency of major and minor malformations even if they do not have the full FAS. Furthermore, some (but not all) studies of "social drinkers" report an increased risk of anomalies suggestive of fetal alcohol effects in their children.

Central Nervous System Dysfunction

The development of the central nervous system is where maternal alcohol has the most devastating effect. For fetal alcohol syndrome children, mild to profound mental retardation is usually present. Autopsies of the brains of infants born to heavy or binge drinkers reveal seriously abnormal patterns of cell migration, while animal experiments demonstrate the profound effect that exposure to ethanol has on the developing CNS.

Mental, motor, and behavioral effects have been reported in human neonates, infants, and children—some at low levels of maternal alcohol use. Poor muscle tone, decreased activity, unusual newborn behavior, and small but significant decrements in mental and motor development are among these effects. Susceptibility of the brain to alcohol is not surprising, since even a single drink significantly suppresses fetal breathing. Furthermore, the retardation seen in FAS is essentially irreversible. The reversibility of lesser fetal CNS effects is not yet known.

Evidence has recently been presented, in studies on either coast, that alcohol consumption in pregnancy is significantly related to increased risk of spontaneous abortion (miscarriage). Increased frequency of stillbirth and perinatal death were reported as early as 1899, and research since that time has generally supported this finding.

Other Effects

Additional fetal alcohol effects that do not fall neatly into the four categories listed above have also been noted: poor condition at birth, sucking problems, and complications of pregnancy are among them. The frequency with which "partial" fetal alcohol effects occur has not been clearly established, but certainly they are far more common than the full fetal alcohol syndrome.

THE AMOUNT OF ALCOHOL THAT CAUSES FETAL EFFECTS

No one can predict, in a specific pregnancy, exactly how the growing fetus will be affected by its mother's drinking. Alcohol freely crosses the placenta, and concentrations in the fetus are at least as high as they are in the mother. Simply stated, if the mother has a martini, so does her developing child. Some babies appear to be impervious even to large doses of alcohol; others are vulnerable. This variable response is seen with many teratogens(b), and the effect on the individual child apparently depends on factors that are unexplored or even unknown. However, many of the fetal effects seen with heavy maternal drinking are clearly related to alcohol use itself, and not to another factor such as smoking or poor diet. Animal studies with nutrition-matched controls support the claim that maternal alcohol consumption produces a variety of harmful effects that approximate those reported in the human fetus.

(b) A teratogen is a substance that may cause birth defects when taken by the mother during pregnancy.

Although one cannot predict what will happen in the individual case, there is risk to the fetus associated with a wide range of drinking patterns. All of the four types of fetal effects listed above are reported when mothers drink heavily during pregnancy. In addition, women who are "alcoholic" by the usual definitions may have a child with the full fetal alcohol syndrome. At lower levels of consumption that are within the social norms of drinking, the risks are less clear. Decreased growth and abnormal physical development have both been reported at an average of one or two drinks daily; so have behavioral and neurological deficits. Of special concern is the low level of drinking found to increase the risk of spontaneous abortion; investigators at Columbia University have estimated that "one quarter of pregnant women who drink [two drinks] twice a week or more will have a spontaneous abortion, half of which will relate to alcohol".(3) With the exception of this study, no major research to date has shown increased fetal risk below one drink per day.

A dose-response curve is apparent in animals for some fetal alcohol effects. That is, large amounts of alcohol produce severe effects on the fetus, while smaller amounts produce lesser effects. Some scientists believe a dose-response curve also exists for humans while others feel that the data do not support such a claim. There is also conflicting evidence as to whether one type of alcoholic beverage is "safer" than another. Nor has a "safe" period of pregnancy been identified. The first trimester, while the organs are forming, is a critical time. In the second trimester, an increased risk of spontaneous abortion may exist if the mother drinks regularly. Growth and brain development are affected by alcohol consumption in the third trimester. In fact, heavy maternal drinking prior to pregnancy and during lactation has also been linked to adverse consequences for the child.

The accumulated evidence implicating alcohol as detrimental to the developing child has led both the Surgeon General of the United States and the American Medical Association to advise that the safest course of action for pregnant women is abstinence. This recommendation is appropriate until more is known about the specific effects of alcohol on the individual fetus, and the dose, if any, at which risk is minimal or non-existent.

THE COST OF FETAL ALCOHOL EFFECTS

Describing the magnitude of the problem posed by excessive drinking during pregnancy is very difficult because data on both the extent of maternal drinking and the frequency of fetal alcohol effects are limited. In this section existing research has been used to estimate the number of women and children affected. Also, a valiant attempt to determine costs has been made in New York State; methods in that study have been used here to obtain figures for the country as a whole. (Calculations are shown in the attached Appendix.)

In the United States, in 1980, there were:

- 110,000 women drinking excessively during pregnancy
- 6,000 infants born with the full fetal alcohol syndrome
- 24,000 infants born with other fetal alcohol effects
- Over 11,000 alcohol-related fetal deaths
- $2.7 billion dollars required in medical, educational, and custodial services for surviving children over their lifespan. (1980 dollars)

In summary, in the United States in 1980, an estimated 82 infants were born each day with fetal alcohol effects, and another 30 were lost in alcohol-related spontaneous abortions. The cost of caring for the survivors during their lifetime will be over two and one-half billion dollars. These tragic estimates will be repeated each year. The economic and social costs of excessive drinking during pregnancy are high indeed.

PREVENTING FETAL ALCOHOL EFFECTS:
CLINICAL EXPERIENCE AT THE UNIVERSITY OF WASHINGTON

Because fetal alcohol syndrome was first identified in this country at the University of Washington, it is fitting that the first major project to prevent FAS was conducted at this University under a grant from the National Institute on Alcohol Abuse and Alcoholism.(c) The project was called the "Pregnancy and Health Program." From 1979 to 1981, the Program provided information on drinking and pregnancy to the entire public and professional community of King County, Washington. It also offered education and treatment to pregnant women who were concerned about their drinking, and evaluation of children possibly affected by alcohol exposure in utero.

The effectiveness of the Pregnancy and Health Program in preventing fetal alcohol effects is now being evaluated. Due to very limited funding, this evaluation will not be completed until next year. Some conclusions can be drawn, however, and I am presenting them because they bear on the matter we are discussing today: the dissemination of information about the risks of drinking during pregnancy.

The Pregnancy and Health Program was established in an area already sensitized to the problem of drinking during pregnancy. Extensive media coverage had been given to the original identification of fetal alcohol syndrome in 1973, and to the research activity that followed. In spite of this, a study conducted before the Program began its public education campaign in 1979 revealed that while the residents of King County were aware that alcohol might be harmful to the fetus, only a small fraction believed that abstinence was indicated. Others stated that only very heavy drinking should be proscribed. Clearly, in King County, awareness of risk was no guarantee that aggressive action would be taken to avoid the risk.

(c) Grant #AA03736, "A Demonstration Project to intervene in Maternal Alcohol Abuse During Pregnancy and Prevent Fetal Alcohol Syndrome"; Ruth E. Little, Principal Investigator, Ann P. Streissguth, Co-Investigator, Gay M. Guzinski, Collaborative Investigator.

There were also serious gaps in the services offered to women who were drinking excessively and pregnant. A survey of health professionals (excluding physicians) indicated that while there was awareness of a possible problem, only a third of those who treated pregnant women routinely recommended that they not drink. When a random sample of obstetricians was interviewed, a third of them said that they did not even discuss alcohol use with their prenatal patients. Furthermore, pregnant problem drinkers were not being seen in the County treatment agencies. In the year prior to the establishment of the Pregnancy and Health Program, only six pregnant drinkers were seen in the County Community Alcohol Centers. Thus professionals providing prenatal care often failed to deal with alcohol use, and those knowledgeable about alcohol use were not in contact with pregnant heavy drinkers. There was clearly a need for action on several fronts; these are described briefly below.

Public Education

The first step for the Pregnancy and Health Program was to provide extensive public information to all citizens in the county. The message was simple and direct, stressing abstinence. The decision to stress abstinence was carefully considered, especially since infrequent light drinking had not been proven harmful. However, there was clearly no risk to the fetus if women did not drink, and the spontaneous aversion to alcohol that occurs during pregnancy supported the decision that this was a realistic goal for most women. Simple, informative public education messages were then distributed throughout the County, reaching an estimated one million residents.

Concurrently, a 24-hour information line staffed by volunteers was established to offer additional information and assistance for women in crisis. In the two years that the Program provided services, over 2,500 calls were received, with about one in every 40 pregnant women in the County asking for information or assistance. Most sought elaboration of the public education message, but some required more service and were seen personally at the Pregnancy and Health Program for education and treatment. The information line was an essential adjunct to the massive public education campaign, and it also served as the main method of self-referral to treatment for pregnant women who were unable to decrease their drinking.

Professional Training

The Pregnancy and Health Program also sought to provide information and training to every professional in King County who might come in contact with the pregnant drinker or her child after it was born. More than 6,000 health and social service professionals participated in formal Pregnancy and Health Program training presentations, while another 7,000 received written informational materials.

Clinical Services

A total of 655 pregnant women, children, and family members received services in person from the Pregnancy and Health Program. Pregnant women were most frequently seen because a professional with whom they were in contact suggested that they seek service. The frequency of professional referrals is a measure of success of the Program's training. In all, nearly 200 pregnant alcohol abusers were treated by the Pregnancy and Health Program—an estimated 15 percent of those in need of service. (In King County as a whole, 20% of women in need of alcohol services received them.(4)) An additional hundred or so pregnant women, who did not have an alcohol problem in the usual sense of the term, also sought advice and support.

Conclusions

Whether the Pregnancy and Health Program prevented fetal alcohol effects is not yet known. However, some important conclusions can be drawn.

- Even in an area as knowledgeable as King County, Washington, there was a need for information about the risks of drinking during pregnancy among both public citizens and professionals.
- Public information resources, when provided, were used both by pregnant women and other concerned persons. Person-to-person telephone contact provided a vital supplement to the intensive public education campaign, allaying concern and guiding callers to help when needed.
- The traditional health and social service agencies in King County initially were not serving women who were drinking and pregnant. After training, professionals were able to identify women who drank heavily and refer them to treatment.
- The cost of public education and professional training in King County over the two years was under $500,000. This is less than the estimated cost of providing lifetime care to three children born with fetal alcohol syndrome.

CLOSING THOUGHTS

In the last ten years, alcohol has been shown to be harmful to the fetus. In large amounts, it is a devastating teratogen, producing serious birth defects. The fetal consequences of moderate doses of alcohol have not been fully delineated, but there is evidence both in humans and laboratory animals that drinking within social norms may produce deleterious effects.

I believe that in the next ten years our work should take new directions. While there is much to be learned about how maternal drinking is related to fetal damage, other urgent questions await. One is the relationship of alcohol use to other areas of reproduction. What are the consequences of heavy alcohol use prior to pregnancy? What are the effects on the infant who receives alcohol via mother's milk? And has the drinking father a role to play in all of this? Each of these questions has important implications for the health of the child and the family.

Another area in which work is urgently needed is the prevention of fetal alcohol effects. In my experience, there are two kinds of drinking women. One is able to choose whether she wishes to drink when she is pregnant. For such a woman, information about alcohol use and its risks, coupled with the natural aversion to alcohol that occurs after conception, may be sufficient to effect a decrease in her consumption and prevent many fetal alcohol effects. The second type of woman has lost the choice of whether or not to drink while pregnant. Identifying these woman and providing effective treatment for them is essential. This requires informed professionals and special resources capable of dealing both with pregnancy and with alcoholism. Programs to effect this prevention are basically not available today.

All fetal alcohol effects are preventable. Now is the time to prevent them. It is also the time to direct scarce resources to the other alcohol-related problems in child and family health noted above that must warrant our concern.

APPENDIX

ESTIMATING NUMBERS AT RISK AND COSTS OF DRINKING DURING PREGNANCY, 1980

1. NUMBER OF PREGNANT EXCESSIVE DRINKERS IN U.S.

-Estimates used for rate of excessive drinking

Drinking over 6 drinks daily (5)	.001
"High Volume/Variability" (6)	.070
"High Volume/Variability" (7)	.017
"Alcohol abuse" (8)	.017
"Problem drinker" (9)	.027

Mean of above estimates =		0.026
-Number of pregnancies in U.S.		
Number of live births (10)	3,600,000	
Estimated rate of spontaneous abortion/stillbirth (3,5)	0.15	
Number of pregnancies required to result in these live births		4,235,300
- Total pregnancies times rate of excessive drinking		110,118

2. NUMBER OF ALCOHOL AFFECTED INFANTS IN U.S.

-Number of live births (10)	3,600,000	
-Rate of FAS (11)	0.0017	
Number of FAS children		5,956
-Rate of other fetal alcohol effects (11)	0.0067	
Number of children with other effec		24,115

3. NUMBER OF ALCOHOL-RELATEI SPONTANEOUS ABORTIONS

-Total pregnancies (see #1)	4,235,300

-Estimates of rate of risk level drinking

1-2 drinks daily (5):	.03
1-2 drinks daily (7):	.024
1-2 drinks daily (12):	.008

Mean of above estimates =	0.021	
-Total pregnancies with drinking at risk levels		88,941
-Rate of alcohol-related spontaneous abortion among risk drinkers (3)		0.125
-Number of alcohol-related spontaneous abortions		11,118

(Note: Late fetal deaths not included in these calculations due to insufficient U.S. data.)

4. COST OF FETAL ALCOHOL EFFECTS (in millions)

FAS only

Cost per case in 1978: (11)	$.172	
(Plus 10% increase for inflation by 1980)	.189	
Total cost for 5,956 cases		$1,129

Other fetal alcohol effects ("ARBD")

Cost per case in 1978: (11)	$.057	
(Plus 10% increase for inflation by 1980)		
Total cost for 24,115 cases		$1,524
Total, all cases		$2,653

5. ESTIMATED NUMBER OF PREGNANT ALCOHOL ABUSERS IN KING COUNTY, WASHINGTON AND NUMBER SEEN AT THE PREGNANCY AND HEALTH PROGRAM 1979-1980

Live Births (by occurrence) 1979-1980 (13)	38,278	
Total pregnancies, adjusting for spontaneous abortion and fetal death (3, 5, 13)	45,168	
Number of pregnant alcohol abusers in King County (9)		1,220
Number of pregnant alcohol abusers seen at Pregnancy and Health Program		183
Percent of all pregnant abusers		15%

SUPPORTING LITERATURE

Specific citations

1. Jones KL, Smith DW, Ulleland CN, Streissguth AP. Pattern of malformation in offspring of chronic alcoholic mothers. Lancet 1: 1267-71, 1973.

2. Little RE, Streissguth AP, Barr HM, and Herman CS. Decreased birthweight in infants of alcoholic women who abstained during pregnancy. Journal of Pediatrics 96: 874-77, 1980.

3. Kline J, Shrout P, Stein Z, Susser M, Warburton D. Drinking during pregnancy and spontaneous abortion. Lancet 2: 176-80, 1980.

4. Washington State Alcoholism Plan, 1981. Department of Social and Health Services, Office on Alcoholism, Olympia, Washington.

5. Harlap S, Shiono PH. Alcohol, smoking, and incidence of spontaneous abortions in the first and second trimester. Lancet 2: 173-76, 1980.

6. Ouellette EM, Rosett HL, Rosman NP, Weiner L. Adverse effects on offspring of maternal alcohol abuse during pregnancy. New England Journal of Medicine 197: 528-30, 1977.

7. Streissguth AP, Martin DC, Buffington VE. Identifying heavy drinkers: A comparison of eight alcohol scores on the same sample. In Seixas, F., Ed. Current in Alcoholism V. II, New York: Grune and Stratton, 1977, pp. 395-420.

8. Sokol RJ. Alcohol and abnormal outcomes of pregnancy. Canadian Medical Association Journal 125: 143-48, 1981.

9. Little RE. Drinking during pregnancy: implications for public health. Alcohol Health and Research World 4: 36-42, 1979.

10. Statistical Abstract of the US: USA Statistics in Brief, 1981. U.S. Bureau of the Census.

11. Russell M. Impact of alcohol-related birth defects (ARBD) on New York State. Neurobehavioral Toxicology 2: 277-83, 1980.

12. Little RE, Worthington B, Davis A, and Durand S. Drinking in 655 consecutive prenatal patients. Unpublished manuscript based on current research in a Seattle prenatal clinic.

Research reviews

1. Eckhardt MJ, Harford TC, Kaelber CT, et al. Health hazards associated with alcohol consumption. Journal of the American Medical Association 246: 648-66, 1981.

2. Little RE, Graham JG, Samson HH. Fetal alcohol effects in humans and animals. Advances in Alcohol and Substance Abuse, Fall, 1982 in press.

3. Rosett HL, and Weiner L. Identifying and treating pregnant patients at risk from alcohol. Canadian Medical Association Journal 125: 149-54, 1981.

4. Sokol RJ. Alcohol and abnormal outcomes of pregnancy. Canadian Medical Association Journal. 125: 143-48, 1981.

5. Streissguth AP, Landesman-Dwyer S, Martin JC, Smith DW. Teratogenic effects of alcohol in humans and animals. Science 209: 353-61, 1980.

Senator **Humphrey**. Thank you, Dr. Little.

I always have to ask how to pronounce your name, Dr. Aase. I beg your pardon.

Dr. **Aase**. Not at all. I am not accustomed, of course, to being the last on the list, with two "A's" to start my name.

I am Jon Aase. I am a pediatrician and dysmorphologist with the department of pediatrics at the University of New Mexico in Albuquerque. I imagine that my reason for being seated here today is that I have had some experience in our part of the world with a large, if I may say, fine-screened survey of a limited population for evidence of fetal alcohol syndrome and fetal alcohol effects. I have also had experience with over 200 children with these diagnoses, and that clinical experience is what I would like to base my testimony on today.

In summarizing what I had hoped to bring to you today, I find that I have been preempted beautifully by Dr. Brandt and all the other speakers on our panel, and it is a little daunting to try to bring to a conclusion some of the eloquent remarks that were made this morning.

Perhaps I can sum it up best by saying this: In our own surveys, the evidence for the existence of fetal alcohol syndrome and fetal alcohol effects was an order of magnitude greater than we had expected to find. As Dr. Brandt pointed out, as many as one in 100 children might be affected in an extrapolation from information available for the general population of this country.

In our survey, we were able to find subgroups of our Southwestern Indian population in which 1 in 50 children are clearly involved, on a very conservative estimate. With figures like this, I think it is safe to say that we have an epidemic of a preventable disease.

The epidemic is one that I have characterized in some educational efforts for our Southwestern audiences as being one of unintentional child abuse of prenatal origin. Prenatal child abuse, if you will, is a preventable disorder, and that is the good news. The bad news is that from the point of view of the practicing physician and from those of us who are attempting to elucidate the causes and fetal effects of alcohol disruption of growth and development, there is no cure and the children are handicapped lifelong.

Because of the bad news, I would like to emphasize the good news—the prevention aspects. From our study, we have one additional point that I think is well to make. In terms of target groups, we have been targeting teenagers in our States as well. But it is clear now from our evidence that women who have had a previous child with some evidence of fetal alcohol effects are between six and eight times more likely to have a subsequent child with that effect, and so we began targeting our educational efforts specifically at mothers who had already undergone the experience of having a damaged child from alcohol.

That, alone, may be some contribution, but there is another that I would like to bring out specifically to Dr. Little and the others of us who are in the investigatory end of things. As has been pointed out before, some 40 percent of women who are severely and chronically alcoholic during pregnancy will give birth to a child with fetal alcohol syndrome. These are women who are drinking a quart of vodka, a gallon of wine or a case of beer every day.

In the latter instance, it is hard to understand how a woman would have time to be pregnant. But I must say that these severe alcohol intakes associated with fetal alcohol syndrome in 40 percent of the instances give rise to a fascinating research question: What protects the other 60 percent?

If we could find out what the protective factors are or those factors which could be used to predict which mothers are at risk for producing babies with fetal alcohol syndrome, coupled with the information we have now about repeater mothers, we might be able to stem the tide of what seems to me to be the single most common, known cause of mental deficiency in the United States today.

[The prepared statement of Jon Aase follows:]

THE FETAL ALCOHOL SYNDROME AND
FETAL ALCOHOL EFFECT

When a woman drinks alcohol during pregnancy, her baby may be born with serious and permanent abnormalities. These birth defects form a pattern which includes unusual facial features, slow growth and mental retardation. In its most severe form, this pattern of abnormalities is called the Fetal Alcohol Syndrome.

While this condition must have existed for centuries, it was first named and described in 1973, by Drs. Jones and Smith in Seattle. Since that time, hundreds of affected children have been discovered in this country and elsewhere, and the consistent features of this disorder have been well established:

> Babies with Fetal Alcohol Syndrome are born smaller than normal, and they continue to grow slowly throughout childhood.
>
> Their head size is especially small, indicating poor brain growth. Malformation of brain structure is common.
>
> Mental retardation of a significant degree is almost always present.
>
> The facial appearance is altered to the extent that affected children look more like each other than like members of their own family.

The first children diagnosed as having the Fetal Alcohol Syndrome were born to mothers who were severely alcoholic during their pregnancy, drinking as much as a quart of vodka, a gallon of wine or a case of beer a day. Once we became alerted to the existence of this diagnosis, however, it became clear that some mothers whose alcohol intake was much less, still gave birth to babies with milder degrees of the same problems. As little as two glasses of whiskey or wine, or three bottles of beer a day during pregnancy may be enough to produce some of the features of this disorder, especially the slow mental development. The present designation for this mild or incomplete form of involvement is "Fetal Alcohol Effect".

It is evident that the more a mother drinks during her pregnancy, the higher the risk of having a baby with some damage from alcohol, and the more severe such damage may be. Still not every mother who drinks will give birth to an affected child. Some babies seem to be protected from the harmful effects of alcohol, for reasons we don't know.

Children with evidence of prenatal damage from alcohol are found in every population group and every social stratum in every state in the Union. In some specific regions, the occurence of this condition is shockingly high, once it is looked for. During the past two years, I have taken part in a survey encompassing parts of several states in the Southwest. Here, the incidence of Fetal Alcohol Syndrome and Fetal Alcohol Effect vary greatly among different areas, but in some places, range as high as one in every fifty to sixty births. The most conservative estimates for the United States as a whole indicate that prenatal alcohol damage is clearly the most common known cause of mental retardation in this country.

Unlike the vast majority of birth abnormalities which affect our children, the Fetal Alcohol Syndrome and Fetal Alcohol Effect are totally preventable. No matter what other factors may be involved, we know that if a woman can stop drinking during her pregnancy, her baby will not suffer from the harmful effects of alcohol. Since there is no known medical treatment to reverse these effects, our attention obviously should be directed toward measures to help women stop drinking during pregnancy, as well as toward further research into the ways alcohol causes such severe and lifelong handicaps in babies exposed before birth.

Presented by:
Jon M. Aase, M.D.
Associate Professor of Pediatrics
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Senator **Humphrey**. You characterize the situation as an epidemic of preventable disease. How long has this epidemic been raging?

Dr. **Aase**. If I may answer that, there is some reason to believe that this has been around for 1,500 years or so. There are even quotations in the Book of Judges in the Bible, where an angel says to the mother of the baby that is going to be Sampson, "So, go ye forth and drink no wine nor strong drink." Maybe they knew something we did not know back that far.

We know that there have been references to babies being born feeble and distempered back in the 1600's and 1700's in England during the gin epidemic in that country. It is clear that this condition has been with us since alcohol has been available. But its late recognition, I think, is based on two facts.

One of the facts is that these children are subtly different from other children with handicaps, and that subtlty may have been enough to hide it from us. The second reason, I think, is that alcohol is our pet drug.

Senator **Humphrey**. I am sorry. I missed that last thing.

Dr. **Aase**. I consider alcohol to be our pet drug, one that we have to believe is safe because it is used so widely.

Senator **Humphrey**. Dr. Little, you spoke about the program you had in King County, Wash., and the fact that you reached 1 million people in your program of public education. How did you reach that million people?

Dr. **Little**. Mr. Chairman, we did everything we could think of. We used the media—television, radio, and newspapers.

Senator **Humphrey**. Public service announcements?

Dr. **Little**. PSA's, yes.

Senator **Humphrey**. What degree of cooperation did you get?

Dr. **Little**. Excellent. We were fortunate to have a good media consultant and the stations worked with us. All three of the major network stations carried our PSA's. They also assisted us in producing them for no charge. So, the cooperation in all the media was excellent.

We put out our own written materials. Our brochures and posters, we put everywhere we could think of—in the diaper services, in the laundromats, and wherever we thought a pregnant woman might be. We put them in maternity shops. We had bus signs so that the captive audiences who rode the buses, which are very numerous in King County, could not be free for a minute from our publicity.

We spoke wherever two people would gather together. We were at all the health fairs. In other words, we tried to be everywhere. The most cost-effective method of providing public information was the media. But I would like to distinguish our two goals: Getting the information out to the public in a cost-effective manner, and reaching the second kind of woman that I mentioned—the woman who needs to come in herself and get treatment. There, the professional who cared for the woman was far more effective than any media message was in getting her to come in for help.

Senator **Humphrey**. You speak of "we." Is this a project of the university?

Dr. **Little**. The University of Washington, yes. There were many people involved.

Senator HUMPHREY. Yes, but you had a project based at the university which steered this program?

Dr. LITTLE. Yes.

Senator HUMPHREY. Have you produced any kind of plain-English publication that others could use to follow your example?

Dr. LITTLE. We are ready to do that, Mr. Chairman. Unfortunately, the funds to do that which were in our last year of our grant are no longer available. They have been folded into the block grant funds, and those have not been released yet by the state.

Senator HUMPHREY. Let me just address a question to the panel and you can answer if you care to. What progress has been made in the last decade or the last several years in raising public awareness on a national basis about this problem?

As I said earlier to our first panel, from my perspective—and admittedly, as is probably your case, I do not have much opportunity to watch television or go to the movies, so I sometimes feel culturally deprived. Maybe I am missing the message, but is it out there?

I do not have the feeling that many people are aware of this or that there is much concern or excitement. Does anyone feel qualified to comment on that?

Dr. BLUME. It is still a battle going forward. We did in New York State exactly what Ruth did. We tried to use every possible medium. I would add to hers bumper stickers and buttons, which you have, and I have some in back if any of the audience would like to wear a fetal alcohol syndrome prevention button. They are good because people come up to you and they say, "What is FAS and why should I be against it," and so on.

Senator HUMPHREY. Yes.

Dr. BLUME. But translating that into clinical practice is a very hard step to make. And that, I think, as Ruth said, has been the hardest. From the vague idea that somehow alcohol might not be a good thing to the concrete application to one's own life is a very difficult step. We are still working on it.

May I just make a comment on the warning label question?

Senator HUMPHREY. Yes.

Dr. BLUME. I agree with you that you do not have to read the label everytime you drink to have some contact with a bottle of beverage alcohol and see that label, and I think that is a very effective way to keep this information current in the minds of people.

The argument that this would alarm women and somehow hurt them or create anxiety is a very disturbing argument to me. It is based on, if I may express my personal opinion, a typical, archaic attitude that women are such nervous creatures and so untrustworthy that they cannot be trusted with the truth and make their own decisions based on fact and must somehow be protected.

I think women should be exposed to everything we know and as much as we know, and be trusted to use their judgment, and I think that is a problem.

Senator HUMPHREY. Dr. Takamine, you wanted to say something?

Dr. TAKAMINE. Just very briefly, to corroborate what Dr. Little and Dr. Blume said, in a specific instance that happened in west Los Angeles very recently, Mr. Chairman, showing the difficulty of getting people to want to become aware and to overcome what I not only call sometimes apathy but sometimes hostility. At a hospital where I practice which has a very large obstetrical population, we brought some very knowledgeable people in one night to talk about women and drinking, particularly teenagers, with the emphasis on FAS and all the manifestations therefrom.

This was widely publicized through all the modalities to which Dr. Little alluded. To say it was discouraging would be an understatement. Everybody had been apprised in the hospital and in the surrounding neighborhood.

Not one physician showed up, and a fair number of citizenry came in, some of them I am sure out of curiosity and some because they had the problem close to them. But research is easy and a problem is something else. Information to education—this is something with which all of us are grappling, and I have no specific, concrete way of how to break this barrier towards the use of what Jon said is America's pet drug.

In Science Magazine, which as you know is a very prestigious magazine, a few months ago they were writing on the problem of marihuana. One sentence—and I do not have the article with me; I have it at home—said that marihuana is the most commonly used illicit drug in America.

The next sentence went, "But alcohol and tobacco are the two most commonly used," and at least they used the word "drug." The tacit implication was that alcohol was legal for everybody, and this is something that goes on. Not only is it not a drug to many people, but beer is the beverage of moderation, you heard recently.

So often we focus on the alcoholism and the abuse, whatever that means, and not just on the simple substance and what it can do to the body. I know I am now sounding much like a clinician, but that is irrelevant. We get overly complicated, I think, and do not start where we should start—at the point of entry, which is the use of alcohol.

Senator HUMPHREY. Yes. Dr. Bissell, how greatly could we reduce this epidemic, or what percentage of youngsters who are now exposed to the effects of alcohol could be spared that if we had adequate awareness of the danger in our society?

Dr. BISSELL. I do not think anybody can really answer that, but certainly a significant number. And I think there are things we could do that we are not doing, and that is pay more attention to the media that the youngsters really listen to, like the rock and roll stations, because even inner-city teenagers will listen to music. They do want to have healthy babies, just like everyone else, and a certain number, I am quite sure, would modify their behavior.

I think there are some other things that we can do, and that is not just concentrate on the physician, but look also at groups like the nursing section of the American College of Obstetrics and Gynecology, because the nurses are giving a tremendous amount of the ante-natal education these days and I think they should not be forgotten.

Senator HUMPHREY. Yes.

Dr. BISSELL. And then the only other thing I would like to say is to reinforce what Dr. Blume was saying. I think we must not listen to that silly argument about women being protected from guilt. It fascinates me that the ones who keep saying repeatedly, "Tell us the truth," are the Sheila Blumes, the LeClair Bissells and the Ruth Littles, and our protectors are—I do not know; it is some form of misguided chivalry, but they are usually males. [Laughter.]

Senator **Humphrey**. Well, one last question, a followup of a question I asked of Dr. Brandt, and that is I asked him about whether alcohol passes through the placenta. I guess we are not sure about that yet, but there is an obvious effect.

Dr. Little, I believe it was you who said earlier that, in lactation, alcohol does enter the mother's milk, and therefore a woman who is drinking while nursing is also sharing the booze with the child.

Dr. **Little**. That is right.

Senator **Humphrey**. That is clear and there is no doubt about that?

Dr. **Little**. Yes, sir, that is correct. It is also correct that alcohol passes through the placenta and the blood levels in the fetus are equivalent to the blood levels in the mother. Our public education message is, "If you have a martini, so does your developing baby."

Senator **Humphrey**. Is that right; exactly the same?

Dr. **Little**. Yes, sir.

Senator **Humphrey**. If the mother is sober, the child is sober, and if the mother is drunk, the child is drunk, or anything in between?

Dr. **Little**. Yes, sir. In fact, I have had women who have had alcohol problems tell me that they have been drinking to quiet their kicking fetus.

Senator **Humphrey**. Dr. Takamine?

Dr. **Takamine**. In fact, there is one added problem that we do not know yet. You say if the mother drinks, the baby drinks. With the enzyme system in the baby and the fetus hardly developed to the degree that it is in the mother, the ability to handle a comparable amount at a similar blood level is markedly reduced.

So, I do not know whether the effect would be exponential or what, but it would be markedly greater in the baby at the same blood level because it does not have the capability or defense mechanisms of dealing in a normal physiological way with the alcohol.

Senator **Humphrey**. So, the effect is longer lasting or more damaging? What are you saying there?

Dr. **Takamine**. I hoped you would not ask that question because, as I say, we really do not know if it is longer lasting. I would think, and this is purely conjectural, Mr. Chairman, that it is probably more damaging if you just do not have the whole defense mechanism or the physiological capability.

If the tissues are much softer in the more formative stages, obviously I think the effect of a comparable blood level would have to be more damaging, but I cannot say I can prove that. But it does cross the placenta; that is a given.

Senator **Humphrey**. Dr. Aase, we are going to have to cut this off, but go ahead.

Dr. **Aase**. To just amplify briefly, because of the developmental events that are taking place in the embryo or in the fetus during the developmental time, we know that those tissues are more susceptible to alcohol because of the effects that they show when the baby is born—the fetal alcohol syndrome.

In addition, we have reason to believe that the baby's response to alcohol is different from the absence of one thing that we see in chronically alcoholic adults, and that is severe liver disease. The baby's liver is not able to respond as an adult's does. Partly because it is not able to detoxify alcohol in the liver, the alcohol may circulate to other tissues and therefore damage them severely.

Senator HUMPHREY. All right, fine. Thank you all for your testimony and your help here today.

Our last panel is comprised of Mr. Rex Davis, who is chairman of the Licensed Beverage Information Council. He is accompanied by Dr. Henry Rosett, associate professor of psychiatry and obstetrics and gynecology, Boston University School of Medicine. Also, as an independent member of the panel we have Dr. Arthur Salisbury, vice president of medical services, March of Dimes.

Good morning. We have to relinquish this room at 2, which is about 40 minutes away, so we will have to bear that in mind. May we begin with you, Dr. Salisbury?

STATEMENT OF ARTHUR J. SALISBURY, VICE PRESIDENT FOR MEDICAL SERVICES, MARCH OF DIMES BIRTH DEFECTS FOUNDATION; AND REX D. DAVIS, CHAIRMAN, LICENSED BEVERAGE INFORMATION COUNCIL, ACCOMPANIED BY HENRY L. ROSETT, ASSOCIATE PROFESSOR OF PSYCHIATRY AND OBSTETRICS AND GYNECOLOGY, BOSTON UNIVERSITY SCHOOL OF MEDICINE; AND PAUL GAVAGHAN, SECRETARY-TREASURER, LICENSED BEVERAGE INFORMATION COUNCIL, A PANEL

Dr. SALISBURY. I am Dr. Arthur J. Salisbury, vice president for medical services, March of Dimes Birth Defects Foundation. As you probably know, and I hope you do, the March of Dimes is now engaged in the prevention and amelioration of birth defects. We are very pleased and glad to be here to speak with you about the effects of the consumption of alcohol by pregnant women.

I will not take your time by repeating what others have told you about fetal alcohol syndrome, but I will say that the March of Dimes is convinced with the following points.

There is a fetal alcohol syndrome which manifests itself in physical abnormalities of several structures of the body and in mental retardation. The fetal alcohol syndrome is seen primarily in infants whose mothers have ingested large amounts of alcohol throughout pregnancy. We do not know how much is too much.

There are lesser manifestations of alcohol effects seen in infants of some women who have drunk varying amounts of alcohol while pregnant. These manifestations include low birth weight due to diminished growth prior to birth. Again, we know nothing about the dose-response relationship.

That is really all we know about the fetal alcohol syndrome, but here are some other suspicions. Not all women are equally susceptible to the fetal damage produced by alcohol. If that were the case, the incidence of fetal alcohol syndrome would be much higher than it is in this country and in Western European countries, where alcohol consumption is a routine part of daily living for most women, pregnant or not.

There probably are associated risks, such as nutritional deficiencies or socioeconomic factors, which interact with alcohol to produce the fetal damage. There well may be certain weeks or months in the pregnancy when alcohol is particularly likely to damage the fetus, but we would not consider any time period to be totally safe if the woman is a heavy drinker.

When fetal alcohol syndrome was first established as a clinical entity, the March of Dimes presented very conservative advice in our public health education materials: If you are pregnant, do not drink; if you drink, do not become pregnant.

I am going to relate our following experience to you at the risk of being called a male chauvinist pig by the women who just preceded me. It soon became apparent that this advice was extremely disturbing to many women. Their response was to write or call, and I might say in great numbers, to our chapters and to the headquarters of the March of Dimes with questions like this: "I did not know I was pregnant and was having a drink or two every day. Shall I have an abortion?" "I have a retarded child. Did I cause this by having a drink every day or so while I was pregnant?" "I drank moderately during all my pregnancies and have three normal children. Why are you trying to mislead us with exaggerations?" That is actual experience, and I do not care if it is chauvinism or not; I have to relate it.

Obviously, our advice was causing anxiety, guilt and disbelief. This is not the way to promote a public health message, especially one which cannot be substantiated with hard scientific data.

The issue was quite different in the case of smoking during pregnancy. In that case, we know very definitely that women who smoke more than 10 cigarettes a day are at increased risk of having a baby with low birth weight and other problems. We do not have such information about alcohol.

We have now modified our materials to stress thoughtful consideration of what is known and what is not known about fetal alcohol syndrome. We are attempting to inform women that they have a decision to make and that heavy drinking is an irresponsible way to treat a developing and growing fetus. Our effort is to inform women that by cutting down or cutting out, they will remove from the baby's environment a substance which is not beneficial and may be harmful. We try to reinforce the natural drive of women to protect their babies before and after they are born.

I have brought copies of our pamphlet on fetal alcohol syndrome, which I did distribute and I think may be up there—I am not sure—and also a poster which is distributed to our chapters, prenatal clinics and physicians' offices. This says, "Think twice. A pregnant woman cannot drink alone. When you have a drink, your unborn baby does too. Excessive use of alcohol during pregnancy may cause severe physical or mental birth defects. Only you can prevent birth defects caused by alcohol." This has had very wide distribution, in association with other posters about smoking that we distribute.

In addition to our public health education efforts, the March of Dimes is supporting research to define the risk of alcohol use during pregnancy in relation to amounts and patterns of consumption, associated factors such as smoking and diet, and the occurrence of fetal alcohol syndrome or partial forms of it.

We most definitely feel that all such research should be prospective; that is to say the subjects in their control should be studied during a current pregnancy, not retrospectively through case records and subsequent interviews.

Thank you.

[The prepared statement of Dr. Salisbury follows:]

Testimony

Presented to

THE SENATE SUBCOMMITTEE

On

ALCOHOLISM AND DRUG ABUSE

By

Arthur J. Salisbury, M.D.
Vice President For Medical Services
March of Dimes Birth Defects Foundation

September 21, 1982

I am Arthur J. Salisbury, Vice President for Medical Services of the March of Dimes Birth Defects Foundation. As you know, the March of Dimes is engaged in the prevention and amelioration of birth defects. Thank you for the opportunity to speak to you about the consumption of alcohol by pregnant women.

I will not take your time in repeating what others have told you about the fetal alcohol syndrome. The March of Dimes is convinced of the following points:

1. There is a fetal alcohol syndrome which manifests itself in physical abnormalities of several structures of the body and in mental retardation.
2. The fetal alcohol syndrome is seen primarily in infants whose mothers have ingested large amounts of alcohol throughout pregnancy. We do not know how much is too much.
3. There are lesser manifestations of alcohol effects seen in infants of some women who have drunk varying amounts of alcohol while pregnant. These manifestations include low birthweight due to diminished growth prior to birth. Again, we know nothing about the dose-response relationship.

That is all we know about fetal alcohol syndrome, but here are some of our suspicions:

1. Not all women are equally susceptible to the fetal damage produced by alcohol. If this was the case, the incidence of fetal alcohol syndrome would be much higher than it is in this country and in western European countries where alcohol consumption is a routine part of daily living for most women, pregnant or not.

2. There probably are associated risks such as nutritional deficiencies or socioeconomic factors which interact with alcohol to produce the fetal damage.
3. There well may be certain weeks or months in the pregnancy when alcohol is particularly likely to damage the fetus, but we would not consider any time period to be totally safe if the woman is a heavy drinker.

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It soon became apparent that this advice was extremely disturbing to many women. Their response was to write or call with questions like this:

> "I didn't know I was pregnant and was having a drink or two every day. Shall I have an abortion?"
>
> "I have a retarded child. Did I cause this by having a drink every day or so while I was pregnant?"
>
> "I drank moderately during all of my pregnancies and have three normal children. Why are you trying to mislead us with exaggerations?"

Obviously, our advice was causing anxiety, guilt and disbelief. This is not the way to promote a public health message, especially one which can't be substantiated with hard, scientific data. The issue is quite different in the case of smoking during pregnancy. In that case, we know very definitely that women who smoke more than ten cigarettes a day are at increased risk of having a baby with low birthweight and other problems.

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I have brought copies of our pamphlet on fetal alcohol syndrome and a poster which our Chapters distribute to prenatal clinics and physicians' offices.

The March of Dimes is supporting research to define the risk of alcohol use during pregnancy in relation to amounts and patterns of consumption, associated factors such as smoking and diet and the occurrence of fetal alcohol syndrome or partial forms of it. We feel that all such research should be prospective (the subjects and their infants and controls should be studied during a current pregnancy) and not retrospectively through case records and subsequent interviews.

Senator HUMPHREY. Thank you, Doctor.

Mr. Davis?

Mr. DAVIS. Thank you very much, Mr. Chairman. I am Rex D. Davis, chairman of the Licensed Beverage Information Council, which was formerly known as the Beverage Alcohol Information Council. On my immediate left is Mr. Paul Gavaghan, who is secretary-treasurer of the council, and on my far left is Dr. Henry Rosett of the Boston University School of Medicine.

With your permission, Mr. Chairman, and I think with your encouragement, I would like to submit a written statement for the record and then briefly summarize it in my oral testimony.

Senator HUMPHREY. Fine.

Mr. DAVIS. We appreciate the opportunity to appear before this distinguished subcommittee to explain the extensive public education and research activities of the Licensed Beverage Information Council with respect to drinking and pregnancy.

The LBIC is a consortium of 10 industry trade associations which represent retailers, wholesalers, producers and importers of wine, spirits and beer. The council was formed as the industry's response to a 1978 scientific study sponsored by the Department of the Treasury which concluded that the public education approach was needed to raise the awareness of American women concerning drinking and pregnancy.

In 1979, after considerable study, the council adopted a multimedia, multiagency strategy, since there was no one group in the health field possessing all the expertise, acceptance and outreach necessary for such a program.

Unfortunately, I do not have time to describe what we now call our phase one program, but it is summarized in my written statement.

Now, I would like to refer to phase two of the public education campaign launched by the council early this year. In this phase, the LBIC has broadened its program beyond drinking and pregnancy to include alcoholism and drunk driving. This expanded program takes into account recommendations by the Departments of Treasury and Health and Human Services in their joint 1980 report to Congress.

A word or two should be said about this HHS-Treasury study which was mandated by Congress under Public Law 96-180 in response to proposed legislation which would have required warning labels on alcoholic beverages.

The study conducted by the two departments involved extensive consultation with leading experts in key scientific and education areas. In their report, the departments agreed at that time to recommend a "broad-based, diverse and highly visible public information campaign on alcohol-related problems."

Mr. Chairman, we in the licensed beverage industry are concerned about the persistent current rumors that a health warning label amendment for alcoholic beverages will be proposed again on the Senate floor. Such an amendment would contravene what the Carter, and later the Reagan administration, have said on this issue, and it would bypass the public hearing process.

Despite all the evidence and knowledge accumulated in an extensive series of consultations with health, research, and education experts by HHS and Treasury, culminating in their recommendation against a warning label in favor of education programs such as ours, those who are absolutely prejudiced against the facts again wish to rush the simplistic warning label concept into law without due analysis and discussion.

Senator Humphrey, under your chairmanship, this subcommittee is developing a substantial body of expertise and knowledge concerning health problems associated with excessive consumption of alcohol. You are well aware that the 1980 Treasury-Health and Human Services study extensively examined the effectiveness of warning labels on alcoholic beverages. This examination included input from experts in the communications, medical and scientific areas, as well as other concerned parties, such as women's groups and alcoholism organizations.

The conclusions of this study, as well as many of those before and after, are that warning labels are not required and are not an effective method of informing the public about the complex health problems associated with excessive alcohol consumption. This is still the case today.

Since early 1979, our Council has fulfilled its pledge of cooperation with the U.S. Government to conduct a public education program as a more viable, effective alternative to warning labels. In good-faith reliance on that cooperative effort with the Government, we have expended substantial resources in conducting a successful program of public education.

In fact, our program is one of the best examples today of private sector cooperation with Government on an important health issue. Officials in the previous and current administrations have cited our program as such an example.

Warning label legislation would denigrate this successful, cooperative program. It would wrongly signal to the public that education efforts are not needed, and it would contravene the extensive study that government agencies and experts have devoted to this issue.

Mr. Chairman, we know that if your Senate colleagues were as well informed about warning labels as you and the other members of this subcommittee, we would not have to be concerned that our good-faith pledge would be breached, and more importantly that the public would be the real losers. Effective education and not simplistic scare tactics is what is required in this problem.

Thank you for the opportunity to speak, Mr. Chairman.

[The prepared statement with attachment of Mr. Davis follows:]

LBIC
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Statement of
Rex D. Davis, Chairman
Licensed Beverage Information Council
To

Senate Subcommittee on Alcoholism and Drug Abuse
Public Hearings of
September 21, 1982

- American Beverage Alcohol Association
- Association of American Vintners
- Distilled Spirits Council of the United States, Inc. (DISCUS)
- National Association of Beverage Importers, Inc.
- National Beer Wholesalers' Association of America
- National Licensed Beverage Association
- National Liquor Stores Association, Inc.
- United States Brewers Association, Inc.
- Wine and Spirits Wholesalers of America, Inc.
- Wine Institute

The Beverage Alcohol Information Council (BAIC), now named the Licensed Beverage Information Council (LBIC), was formed as the industry's response to a 1978 study by the U.S. Department of the Treasury which concluded that the public education approach was needed to raise the awareness of American women concerning drinking and pregnancy.

At a news conference in February, 1979, Treasury officials called for the industry to undertake this responsibility. Ten industry trade associations formed the BAIC and pledged its cooperation with the government. We agreed to conduct a broad-based public awareness campaign because we agreed with experts who have concluded that education is the better alternative to simplistic regulatory approaches, such as a health warning label.

The Council faced a complex challenge. The fetal alcohol syndrome itself was, and is, a controversial issue in scientific, medical and government circles. Medical experts advised us to avoid needlessly scaring expectant mothers, many of whom had been frightened or confused by a variety of reports. Our objective was to motivate as well as inform.

After considerable study, the Council adopted a multi-media, multi-agency strategy since there was no one single group in the health field possessing all the expertise, acceptance and outreach necessary for such a program.

Rather than repeat a description of the Council's phase I program, attached is a brochure which summarizes projects in the public education campaign on drinking and pregnancy (Appendix A).

While the Beverage Alcohol Information Council is the first industry-wide public education effort, it is by no means the only activity in this field. Industry trade associations at the national, state and local level carry on extensive public education campaigns. In addition, many alcohol beverage companies have their own public education efforts and research support programs.

Phase II of the BAIC public education campaign was launched early this year. Phase II builds on the successes of our Phase I activities, but greatly expands our past efforts. The Beverage Alcohol Information Council has broadened its charter beyond drinking and pregnancy. In the process of this expansion, the BAIC name has changed to Licensed Beverage Information Council. The expanded program takes into account recommendations by the Departments of Treasury and Health and Human Services in their joint 1980 report to Congress.

We have thoroughly investigated the various areas of concern covered by the 1980 report, and we have discussed those areas with medical and other professionals in relevant fields. As a result, we have developed the following strategy for Phase II of our public education program.

First, continued attention to the problem of drinking and pregnancy. Phase I of the Council's program enhanced public and professional awareness of drinking and pregnancy. This major public education campaign is being continued with emphasis on outreach effort, scientific research and medical education. LBIC has been continuously active in answering requests concerning this issue and is now recognized as a prime public information source on fetal alcohol effects.

Second, an expansion of the Council's public education activities to include the field of alcoholism. This complex subject is currently being addressed by a variety of private and governmental agencies. Organized labor as well as corporate management are becoming increasingly aware of this illness as it affects employee work performance. And, the medical profession increasingly emphasizes the subject in medical schools, through publications which reach the practicing physician, and through courses on diagnosis and treatment.

There are several reasons why alcoholism is being included in the LBIC Phase II public education efforts. Alcoholism is closely related to some of the problems cited in the 1980 Treasury/Health and Human Services Report. The subject provides an open-ended framework for the addition of new research. The causes of alcoholism are multiple. Finally, alcoholism triggers spinoff medical disorders and other related problems.

In its Phase II effort, the Council will generate awareness that it has widened the scope of its campaign to educate the public to include alcoholism. The medical and social consequences of this complex illness will be stated in a calm, varied perspective. The Council will focus attention on the vast general audience as well as specific populations. We will emphasize that alcoholism is an illness and, most importantly, we will state what is known from research and offer messages of hope that pointedly reinforce the idea that alcoholism is identifiable and treatable.

Here are some specific ways in which we hope to accomplish further progress in the continuation of our education and research campaign:

* An important part of the Council's work has been the funding of basic cooperative projects in which authoritative groups and experts have informed targeted audiences about drinking and pregnancy. A good example is

the medical publication and hospital intervention project conducted by Henry L. Rosett, M.D. His intervention and education package is being introduced to hospital practice and his model is being adopted at major medical schools. Dr. Rosett's outreach to the medical profession is outstanding. The Swedish government has adopted Dr. Rosett's approach in its training program for midwives.

We believe Dr. Rosett's work represents a durable, landmark contribution to actually reduce the fetal alcohol syndrome problem. In view of this, the Boston University School of Medicine is one of our basic building blocks in Phase II of our drinking and pregnancy campaign.

* The Council envisions cooperative projects involving new publications during Phase II. One possibility is a booklet for distribution to women's organizations and civic groups that would include program ideas for use with their members. The American Council on Alcoholism's popular leaflet on drinking and pregnancy has been translated into Spanish. It answers the most often asked questions on drinking and pregnancy. The leaflet will soon be distributed through the Council's network of local affiliated chapters, hospitals and clinics.

* We plan to continue to cooperate with the March of Dimes and other respected national groups which can agree on the following points: Alcoholism is a complex illness with diverse causes and varying manifestations with no single alcoholic prototype; alcoholism is identifiable, and alcoholism is treatable.

* Certain major groups offer particular outreach and have been invited to enhance the Council's public education campaign on alcoholism. We have already embarked on a cooperative project with the Alcohol and Drug Problems Association of North America (ADPA).

* The Council also has a cooperative effort under way with the American Council on Alcoholism which is a key conduit for dissemination of information.

* Arrangements will be made to provide reprints of Dr. Jack Mendelson's upcoming "Alcoholism: Research, Diagnosis and Treatment" review paper to selected medical organizations. Arrangements are being made with another scientific authority on alcoholism to develop a paper for distribution to health professionals. We hope that both of these authorities will be spokesmen for the alcoholism portion of the Council's Phase II program.

* The well known public relations firm of Hill & Knowlton will handle the Council's media publicity program during Phase II, as it did in Phase I. Hill & Knowlton will build on publicity efforts conducted to date using new approaches to generate broader coverage.

Some of the highlights of the planned media publicity program are: Preparation of an expanded background statement using the findings of the 1980 Treasury/Health and Human Services Report and quotes from Council-funded experts. Emphasis will be placed on alcoholism including a specific sub-campaign theme: "Alcoholism, the Treatable Disease."

Prepared features will be distributed to the 3,000 small and weekly newspapers. Attention will be focused on the alcoholism and medical press to alert health care professionals to new information developed through Council funding. Council funded experts such as Drs. Mendelson, and Rosett will be offered for interviews with network and local broadcast programs.
Radio spots will be produced and fed over the Associated Press and United Press International Audio lines to more than 16,000 radio stations. Additional spots will be run on a timely basis as during the holdiay season or to announce new Council publications.

Three public service announcements will be produced in Spanish for use by radio stations in heavily populated hispanic areas. Three similar spots will be produced in English. The six spots will address both drinking and pregnancy and alcoholism as a treatable disease.

During Phase I, an effective and widely distributed educational tool has been the poster in both English and Spanish advising pregnant women to consult their physicians on all matters of diet and health including alcohol consumption. In Phase II, Hill & Knowlton will work to expand the distribution of printed materials through a network of respected national organizations. Currently, for example, the Council is cooperating with the Health and Human Services Office of Health Promotion by sponsoring a joint project involving a poster and pamphlet on drinking and pregnancy. These materials are being developed by Health and Human Services as part of its Healthy Mothers/ Healthy Babies campaign. It is our understanding that tomorrow, September 22, in New York City, Dr. C. Everett Koop, Surgeon General of the United States will make an official announcement of the Healthy Mothers/Healthy Babies campaign including LBIC's participation.

That is a brief summary of the activities we plan as Phase II of our public education program. Many of the projects are well under way while others are in the development stage.

While the LBIC (BAIC) is a public education program conducted by the United States alcohol beverage industry, we work closely with governmental agencies. For example, on December 21, 1981, the U.S. Department of Health and Human Services issued a press release announcing the initiation of the BAIC Phase II program. In the release Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, described the new campaign as "an example of private sector participation in an important health education program."

In a statement made on February 24, 1982, before the Senate Subcommittee on Alcoholism and Drug Abuse, Mr. Carlton E. Turner, Senior Policy Advisor for Drug Policy at the White House, made favorable reference to the Beverage Alcohol Information Council.

On the same date and before the same Senate Subcommittee, Dr. William Mayer, Administrator of the Alcohol, Drug Abuse, and Mental Health Administraiton, described the LBIC (BAIC) program in considerable detail and with approval.

As recently as September 13, 1982, in a speech before the Distilled Spirits Council of the United States, John M. Walker, Jr., Assistant Secretary of the Treasury (Enforcement and Operations) stated:

> "However, I am pleased to see that, as is usually the case, your industry is playing a leadership role in

> responding to this problem (drunk driving) without prodding from the Federal Government..."
>
> "I also applaud the work of the LBIC in drawing public attention to the problems of fetal alcohol syndrome in pregnant women and the problem of alcohol abuse generally."

We are pleased that the Licensed Beverage Information Council has received international as well as national recognition as a model of private sector participation in an important health education program. Last October I was invited to speak at an alcoholism conference in Johannesburg, South Africa to inform participants about the highly credible LBIC public education program. In early June I was a guest participant in a symposium on Alcohol, Health and Society in Amsterdam. Also, we have received inquiries concerning the LBIC (BAIC) program from governmental agencies, universities and private firms in other countries.

In a recent development, the Licensed Beverage Information Council agreed to expand its charter to include the problem of drunk driving. We believe this action is warranted by reason of the national concern that has developed due to the serious social consequences resulting from this problem. Already the Council has under consideration a cooperative effort with the Outdoor Advertising Association of America for alerting the public to the dangers associated with drinking and driving.

Those of us on the Licensed Beverage Information Council believe that an effective and responsible public education program is an important contribution to meeting our social responsibility for the benefit of the public and health care professionals.

Mr. Chairman, we in the licensed beverage industry are concerned about the persistent current rumors that a health warning label amendment for alcohol beverages will be proposed again on the Senate floor. Such an amendment would contravene what the Carter and later the Reagan administrations have said on this issue, and it would bypass the public hearing process. Despite all the evidence and knowledge accumulated in an extensive series of consultations with health, research and education experts by HHS and Treasury, culminating in their 1980 Report to Congress which recommended against a warning label in favor of education programs such as ours, those who are absolutely prejudiced against the facts again wish to rush the simplistic warning label concept into law without due analysis and discussion.

Senator Hunphrey, under your chairmanship, this Subcommittee is developing a substantial body of expertise and knowledge concerning health problems associated with excessive consumption of alcohol. You are well aware that the 1980 Treasury/Health and Human Services study extensively examined the effectiveness of warning labels on alcohol beverages. This examination included input from experts in the communications, medical and scientific areas as well as such other concerned parties as women's groups and alcoholism organizations. The conclusions of this study as well as many of those before and after are that warning labels were not required and are not an effective method of informing the public about the complex health problems associated with excessive alcohol consumption. This is still the case today.

Senator HUMPHREY. Thank you, Mr. Davis. Let me say that with respect to warning labels on beverages, I agree with you, but only partly. I think it is a gratuitous insult to the American people to have a warning on an alcoholic beverage container that alcohol can be harmful to health. I think everybody knows that, just as everyone knows that cigarette smoking can be harmful to health.

But on the other hand, as I have said a number of times this morning, I find that there is a very low perception and awareness of the likely effects on unborn children of alcohol consumption by their mothers. If your organization is willing, and has indeed engaged on its own at its own expense in public education campaigns on this score, why do you oppose a warning label about the effect on unborn children of alcohol consumption?

I mean, if you are willing to underwrite public service announcements, what objection do you have to printing that on your container?

Mr. DAVIS. Yes, sir. You made two or three points and if I could respond to one in the beginning, I heard today, as you did, the American Medical Association, recommend a label to be placed on alcohol. That warning completely overlooks the fact that there is a considerable body of medical evidence that moderate use of alcohol is actually beneficial to your health. We have the Kaiser-Permanente studies and many others which do show that people who use alcohol moderately, in fact, in some cases such as coronary disease are at less risk.

Senator HUMPHREY. Yes, but we are talking in this case about the unborn. There is no evidence that this is helpful to the unborn in any amount, is there?

Mr. DAVIS. Yes, sir, that is true. I might respond that in this whole area, the Department of the Treasury funded two studies during this fetal alcohol syndrome era, and those studies showed—and, Paul, you can come back at me if I am wrong—that 85 percent of the women in the country were aware of the fact that, certainly, excessive alcohol could be injurious to the fetus.

That is a very high level, and that level of awareness was before the campaigns that we have conducted—extensive campaigns of public service announcements. We have posters that were good, as well as the campaigns that are being conducted by the March of Dimes and other organizations which we have cooperated with.

This was cited in the Treasury study which, as we have mentioned, was very extensive and very complete. For example, the advice to pregnant women to totally abstain from alcohol has been attacked by scientific groups, and I have here citations that I would be happy to put in the record. But a scientific group analyzed the evidence and found that there was no basis for a warning for complete abstinence.

[NOTE: The material referred to was retained in the files of the committee.]

Mr. DAVIS. In the same journal in which this was reported, there was an editorial pointing out that it is counterproductive to provide warnings of any kind where they cannot be scientifically justified. The title of the editorial is called "Meddling With Science," and they pointed out that people are being warned constantly about all kinds of things, to the point that if these warnings are used inappropriately, people get to the point where they completely ignore them.

Senator HUMPHREY. Yes, that is true, no doubt about that. There is overkill. But at the same time, I am not sure I quite got an answer to my point of curiosity. And I commend your industry for its record; it has one of the best, if not the best, in the country for spending its own money in a responsible way to educate people about the dangers of excessive alcohol use.

But, again, I ask if you are willing to have public information campaigns about the danger of drinking while pregnant—I am not talking about excessive drinking, but just drinking in general while pregnant—why is that any different than putting a simple label on a bottle?

Mr. DAVIS. Well, of course, I am not an expert in this field, but I can refer back to the Treasury study which did involve many experts, and there were two reasons why. Some of the people who were consulted about using a fetal alcohol syndrome warning label—the feedback from those women's groups was, you know, we have drunk driving, we have alcoholism; why single out this particular issue?

Another point was that by using this—and this was made by the communications experts, et cetera—by highlighting one of the possible problems related to alcohol, then you may mislead people as to the importance of others, such as drunk driving and alcoholism.

Senator HUMPHREY. Well, no doubt about that, but they are getting their fair share of attention. Your objection to labeling with regard to consumption while pregnant is, if I understand you, that this draws attention to only one particular issue?

Mr. DAVIS. Yes, sir. It has also been pointed out that if you accept this, which, by many people, is not considered to be an effective way of communicating knowledge, particularly when you have such a complex problem as the one we are discussing, it is very easy for Congress to pass a law or for a group of health organizations and other people to say, "OK, we have put on a warning label. Now, our job is finished; we can turn our attention to other matters."

Senator **Humphrey**. Well, does your organization disagree with the testimony we have heard this morning that the effects of alcohol on the unborn are an epidemic in this country and that almost immediate and dramatic results can be obtained if enough people are aware of the problem and act rationally?

Mr. **Davis**. Of course, there were, I think, two points made. One of them is an awareness of a problem, and then, of course, the ability to get treatment and to intervene. I certainly would like Dr. Rosett, since he is an expert in this field, to respond to that more fully at such time as you are ready.

Senator **Humphrey**. Sure. Dr. Rosett?

Dr. **Rosett**. Senator Humphrey, I appreciate the invitation to discuss the effects of alcohol on the fetus and the role which the Government and voluntary sectors should play in information dissemination. I also am shortening my presentation to fit in with the time schedule but the full testimony has been submitted, together with three reprints of work that we have published.

My perspectives on this problem have developed through experience as a psychiatrist, as a medical educator and as an active researcher in fetal alcohol effects. This varied experience contributes to my broad view of this problem.

Between 1974 and 1979, we conducted a prospective study of alcohol consumption at various stages of pregnancy at the Boston City Hospital prenatal clinic. Over 1,700 women were interviewed, and 9 percent reported heavy drinking during pregnancy. The minimal criteria of heavy drinking was consumption of at least 45 drinks a month and at least 5 or 6 drinks on some drinking occasions.

However, the average alcohol consumption for the heavy drinkers was close to 9 drinks a day, and the mean daily absolute alcohol use reported by the heavy drinkers was 10 times higher than that of the moderate drinkers.

An intervention program was innovated as part of the research design. Women who reported heavy alcohol use were informed that they had a better chance of having a healthy baby if they stopped drinking. They were encouraged to participate in individual counseling sessions at the time of their routine appointments.

Two-thirds of the women who participated in at least three sessions with a project psychiatrist and counselor stopped drinking heavily.

We have reported data on the first 322 offspring born to women who participated. More infants born to the 27 women who continued to drink heavily throughout pregnancy were growth-retarded, jittery, and exhibited malformations than offspring born to the moderate and rare drinkers.

Infants born to women who had been drinking heavily and stopped in midpregnancy showed more normal growth. No cases of the fetal alcohol syndrome were identified at birth. However, on subsequent clinical examination, FAS was diagnosed in two children, both born to women who drank heavily throughout pregnancy.

Now, these findings have been replicated with an additional 469 infants. The benefits to offspring from reduction of alcohol consumption in midpregnancy which we observed have also been reported in clinical observations from Sweden and from Germany.

Programs for early identification and treatment of women who drink heavily during pregnancy should be developed. Obstetricians and other health care professionals who treat the pregnant women can be trained to obtain a systematic drinking history from each new patient and counsel those women whose infants are at risk for fetal alcohol effects.

A pregnant woman who cannot reduce her drinking after she has been informed that it will help her to have a healthier child is severely addicted. Her offspring are at risk. Existing alcohol treatment resources should be adapted to meet the special needs of these patients.

Mass media campaigns have limited therapeutic effect on those women who abuse alcohol. Direct counseling from the physician who provides prenatal care is a more effective strategy. The NIAAA 1982 focus groups explored attitudes of pregnant women and their husbands. Doctors were considered to be the most credible source of information about pregnancy. The participants also reported that they found scare tactics regarding FAS offensive. Our clinical experience supports these NIAAA findings, and they are very similar to the ones that Dr. Salisbury reported that the March of Dimes has had.

We have consulted with women who have experienced unnecessary fear and guilt that their consumption of small amounts of alcoholic beverages caused abnormalities in their children which probably were due to other factors. Parental guilt and anxiety create stress which is detrimental to the pregnancy, detrimental to the mother-child relationship, and also detrimental to the marital relationship between the parents.

The credibility of the strong evidence of the dangers to the fetus from heavy drinking and alcoholism is weakened through exaggeration of possible dangers from small amounts of alcohol. Physicians are more likely to accept information when it is presented with scientific quantification and documentation. They are skeptical of a simplistic approach. They look for information which is relevant to their patients' problems.

The Boston City Hospital prenatal clinic research program from 1974 through 1979 was funded through NIAAA. At that time, we saw the need to direct increased effort to education of physicians so that they could identify and treat problem drinking within their patient populations. The fetal alcohol education program at Boston University's School of Medicine was developed in 1980 to meet these needs, and has been funded by the Licensed Beverage Information Council. An extensive report on our program activities is contained in the written statement.

We recommend that more educational efforts on fetal alcohol effects be directed toward health care professionals. The ultimate goal of information dissemination is behavioral change. As Dr. Ruth Little has stated, and we agree with her, awareness of risk is no guarantee that aggressive actions will be taken to avoid that risk. Techniques that change behavior during pregnancy are needed if serious attacks on this significant public health problem are to succeed.

We agree that the existing health care network can be modified in a costeffective manner. Physicians trained in identification of heavy drinking and in supportive counseling as a part of prenatal care can improve the health of both mother and infant.

Thank you.

[The prepared statement of Dr. Rosett and the three reprints referred to follow:]

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TESTIMONY TO BE PRESENTED BEFORE

THE UNITED STATES SENATE SUBCOMMITTEE ON ALCOHOLISM AND DRUG ABUSE

SEPTEMBER 21, 1982

By Henry L. Rosett, M.D.

Associate Professor of Psychiatry

and Obstetrics and Gynecology

Boston University School of Medicine

Senator Humphrey and Subcommittee Members:

I appreciate the invitation to discuss with you the effects of alcohol on the fetus and the role which federal, state, and local governments as well as the voluntary sector should play in information dissemination. My perspectives on this problem have developed through clinical experience as a psychiatrist for the past 26 years, as a medical educator for 20 years, a Career Teacher in the Addictions for 10 years, and as an active researcher in the field of fetal alcohol effects for the last 8 years. I served as chairman of the Fetal Alcohol Study Group of the Research Society on Alcoholism between 1975 and 1981 and chaired the section on Neurochemical and Behavioral Effects of Ethanol on the Fetal Central Nervous System at the 1982 Gordon Research Conference on Alcohol. This varied experience contributes to my broad view of this problem which I plan to draw upon in my testimony.

Between 1974 and 1979 we conducted a prospective study of alcohol consumption at various stages of pregnancy at the Boston City Hospital Prenatal Clinic. Over 1700 women were interviewed and 9% reported heavy drinking during pregnancy. The minimal criteria of heavy drinking was consumption of at least 45 drinks a month and at least 5 or 6 drinks on some occasions. However, the average alcohol consumption for the heavy drinkers was closer to 9 drinks a day with a quarter of the group consuming between a pint and a quart of vodka daily. Median daily absolute alcohol use reported by heavy drinkers was 10 times higher than that of the moderate drinkers. An intervention program was incorporated in the research design. Following the interview survey, women who reported heavy alcohol use were informed that they had a better chance of having a healthy baby if they stopped drinking. They were encouraged to participate in individual counseling sessions conducted in the prenatal clinic at the time of their routine appointments. Two thirds of the women who participated in at least three sessions with the project psychiatrist and/or counselor stopped drinking heavily.

Data on the first 322 offspring born to women who participated in the survey demonstrated that more infants born to the 27 women who continued to drink heavily throughout pregnancy were growth retarded, jittery, and exhibited malformations than offspring born to the moderate and rare drinkers (1). The incidence of abnormalities or growth retardation did not differ among the infants born to women who had been drinking heavily and stopped in mid-pregnancy and those born to moderate and rare drinkers. No cases of Fetal Alcohol Syndrome were identified at birth; however, on subsequent clinical examination, FAS was diagnosed in two children, both born to women who drank heavily throughout pregnancy. (This data is discussed in more detail in attached paper.) These findings have been replicated with an additional 469 infants. The larger sample enabled us to employ statistical techniques which demonstrated that alcohol's effects were independent of 8 other risk factors. (A report on this group is currently being peer-reviewed prior to publication.) The benefits to offspring from reduction of alcohol consumption in mid-pregnancy which we observed have also been reported in clinical observations from Sweden and Germany.

Both clinical and epidemiological studies with humans have inherent limitations which can be overcome in experimental studies with animals. They allow for more precise investigation of dose response, effects at different stages of gestation, and isolation of risk factors. An adverse effect of high doses of alcohol has been demonstrated in research with several species including mice, rats, miniature swine, beagle dogs, and monkeys (2). Early experiments demonstrated that low doses of alcohol can cause an effect on brain and behavior without altering growth or morphology (3). More recent experiments have incorporated extensive behavioral testing and have demonstrated that a threshold exists below which there have been no measureable effects on growth or behavior (4). Experiments have also demonstrated that hyperactivity and learning problems observed in younger animals exposed to alcohol _in utero_ tend to diminish as the animals mature (5). This has important implications for rehabilitation programs for FAS children. While dosage levels from one species cannot be directly transposed to another species because of metabolic differences, there have been several epidemiologic studies which found no increased risk from moderate alcohol consumption (6-9).

Programs for early identification and treatment of women who drink heavily during pregnancy should be developed. Obstetricians and other health care professionals who treat the pregnant woman can be trained to obtain a systematic drinking history from each new patient and counsel those women whose infants are at risk for fetal alcohol effects (10). A pregnant woman who cannot reduce her drinking after she has been informed that it will help her to have a healthier child is severely addicted; her offspring are at risk. Existing alcohol treatment resources should be adapted to meet the special needs of these patients.

This may also require the development of new programs including residential treatment, day care centers, and women's support groups.

Mass media campaigns may increase the general level of awareness in society of the danger of heavy drinking during pregnancy. However, they have limited therapeutic effect on those women who abuse alcohol (11). Direct counselling from the physician and health professionals who provide prenatal care is a more effective strategy. The NIAAA 1982 alcohol abuse prevention campaign reported, after exploring attitudes of pregnant women and their husbands in focus groups, that.doctors are considered to be the most credible source of information about pregnancy. The participants also reported that they found scare tactics regarding FAS offensive (12).

Our clinical experience supports these findings. We have consulted with women who experienced unnecessary fear and guilt that their consumption of small amounts of alcoholic beverages cause anomalies in their children which probably were due to other factors. Parental guilt and anxiety create stress which is detrimental to the pregnancy, the mother-child relationship, and the marital relationship of the parents.

The credibility of the strong evidence of the dangers to the fetus from heavy drinking and alcoholism is weakened through exaggeration of possible dangers from small amounts of alcohol. In our experience health care professionals are more likely to accept information when it is presented scientifically with quantification and documentation. They recognize the complexity of issues and are skeptical of a simplistic and moralistic approach. They look for information which meets scientific standards and is relevant to their patient populations.

The Boston City Hospital Prenatal Clinic Research Program from

1974 through 1979 was funded through NIAAA. At that time we saw the need to direct increased effort to education of physicians and other health care providers so that they could identify and treat problem drinking within their patient populations. The Fetal Alcohol Education Program at Boston University School of Medicine was developed in 1980 to meet these needsand has been funded by the Licensed Beverage Information Council (previously named the Beverage Alcohol Information Council) as well as the Distilled Spirits Council of the United States.

During the last 3 years Ms. Lyn Weiner, M.P.H., and I have presented data about fetal alcohol effects at 40 medical and scientific conferences. We have developed a package of 35 mm slides and a teacher's manual which has been used by medical educators at 15 different centers. We have published 10 papers in peer-reviewed journals which were directed toward a wide spectrum of clinicians who treat pregnant women at risk. Four additional papers have been completed and are currently under peer review or in press. We have also written chapters which have been incorporated in 4 medical text books and 2 chapters are in press.

Our exhibit at the 1980 annual meeting of the American College of Obstetrics and Gynecology received a prize award for scientific merit. Other favorable response to our teaching program can be inferred from the large number of reprint requests from around the world as well as from the evaluations which were returned to us following the utilization of our teaching package.

We recommend that more educational efforts on fetal alcohol effects be directed toward health care professionals. The ultimate goal of information dissemination is behavioral change. As Dr. Ruth Little et. al. have stated in a report on a public awareness campaign in a northwestern metropolitan county (13), "Awareness of risk is no guarantee that aggressive action will be taken to avoid that risk ... Techniques that change behavior during pregnancy are needed if a serious attack on the significant public health problem are to succeed."

We agree completely with Dr. Little on this point and believe that the existing health care network can be modified in a cost effective manner. Physicians trained in the identification of heavy drinking and in supportive counseling as part of prenatal care can improve the health of both mother and infant.

This testimony is supplemented by three publications which describe our clinical and educational activities more fully and consider many issues in greater depth than it was possible to present today: "Strategies for Prevention of Fetal Alcohol Effects," "Behavioral Evaluation of Fetal Alcohol Education for Physicians," and "Summary and Recommendations: NIAAA Prospective Fetal Alcohol Studies."

REFERENCES

1. Rosett HL, Weiner L, Edelin KC. Strategies for prevention of fetal alcohol effects. Obstet Gynecol 57:1-7, 1981.

2. Rosett HL. The effects of alcohol on the fetus and offspring. Alcohol and Drug Problems in Women. Ed. by OJ Kalant, N.Y. Plenum, 1980, pp 595-652.

3. Abel EL. The fetal alcohol syndrome behavioral teratology. Psychol Bull. 87:29-50, 1980.

4. Abel EL. In utero alcohol exposure and developmental delay of response inhibition. Alcoholism 6:369-376, 1982.

5. Sonderegger TB, Calmes H, Corbitt S et al. Lack of persistent effects of low-dose ethanol administered postnatally in rats. Neurobehav Toxicol Teratol 4:463-468, 1982.

6. Ouellette EM, Rosett HL, Rosman NP et al. Adverse effects on offspring of maternal alcohol abuse during pregnancy. N Eng J Med 297:528-530, 1977.

7. Tennes K, Blackard C. Maternal alcohol consumption, birth weight and minor physical anomalies. Am J Obstet Gynecol 138:774-780, 1980.

8. Kaminski M, Rumeau-Rouquette C, Schwartz D. Consommation d'alcool chez les femmes enceintes et issue de la grossesse. Rev Epidemiol Sante Publique 24:27-40, 1976.

9. Hingson R, Alpert JJ, Day N et al. Effects of maternal drinking and marijuana use on fetal growth and development. Pediatrics, in press.

10. Weiner L, Rosett HL, Edelin KC. Behavioral evaluation of fetal alcohol education for physicians. Alcoholism 6:230-233, 1982.

11. Lyons JP, Welte JW, Brown J et al. Variation in alcoholism treatment orientation: differential impact upon specific subpopulations. Alcoholism 6:333-343, 1982.

12. Overend RB. You can say no to alcohol, government media campaign tells teens and women. Traffic Safety July/August, 18-29, 1982.

13. Little RE, Grathwohl HL, Streissguth AP et al. Public awareness and knowledge about the risks of drinking during pregnancy in Multnomah County, Oregon. Am J Pub Health 71:312-314, 1981.

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Strategies for Prevention of Fetal Alcohol Effects

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The effects of alcohol on the fetus include a wide range of problems; the complete fetal alcohol syndrome is the extreme end of the spectrum. At critical doses alcohol has the potential for multiple adverse effects on the maternal-placental-fetal system. Variability of outcome probably is related to individual differences in drinking patterns as well as in biologic susceptibility. At Boston City Hospital Prenatal Clinic, therapy was provided for pregnant women who reported drinking heavily. Reduction in maternal alcohol consumption before the third trimester was associated with improved neonatal outcome. The obstetrician's office is a potential site for prevention programs. A 10-question drinking history enables physicians to identify pregnant women at risk. Supportive counseling focused on reduction of alcohol use can be integrated with regular prenatal care. Pregnant women who do not respond promptly should be referred to specialized treatment programs. This strategy has the potential to improve the health of both mother and infant. *(Obstet Gynecol 57:1, 1981)*

Adverse effects on fetal development due to heavy drinking by the pregnant woman have been of medical concern for more than 250 years.[1] Interest in the problem has waxed and waned with changes in social attitudes. Current medical concern has been stimulated by the recognition of a specific pattern of dysmorphology called the fetal alcohol syndrome (FAS).[2,3]

Diagnosis of FAS

A review of the signs observed in 245 cases from around the world[4] served as the basis of minimal criteria for the diagnosis of FAS recommended by the Fetal Alcohol Study Group of the Research Society on Alcoholism.[5] The study group concluded that "the diagnosis of FAS should be made only when the patient has signs in each of the three categories:

1) Prenatal and/or postnatal growth retardation (weight, length, and/or head circumference below the tenth percentile when corrected for gestational age)
2) Central nervous system involvement (signs of neurological abnormality, developmental delay or intellectual impairment)
3) Characteristic facial dysmorphology with at least two of these three signs:
   a) microcephaly (head circumference below the third percentile)
   b) micropthalmia and/or short palpebral fissures
   c) poorly developed philtrum, thin upper lip, and/or flattening of the maxillary area."

FAS can sometimes be diagnosed in the neonate. However, the syndrome may not be recognized until postnatal growth retardation and developmental delay become apparent at 1 or 2 years. In addition, the characteristic facial anomalies may be more easily discerned after the newborn period (Figure 1).

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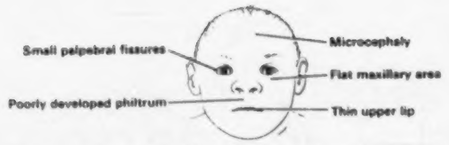

Figure 1. Characteristic facial dysmorphology of patients with fetal alcohol syndrome.

Children who demonstrate the signs of FAS often display other, less specific malformations. These may involve the eyes, ears, nose, and throat as well as the cardiovascular, genitourinary, and musculoskeletal systems.[4,6]

Estimates of the incidence of FAS usually range from 1 in 600 to 1 in 1500 live births. Estimates as high as 1 in 50 live births have been made for some American Indian reservations. Differences in frequency of FAS probably result from variations in drinking practices around the world, as well as from genetic, environmental, and other risk factors. Virtually all infants diagnosed as having FAS have been born to chronic alcoholics who have been drinking heavily throughout pregnancy.

Other Adverse Effects of Alcohol

Clinical observations and prospective studies suggest that the complete FAS is the far end of the spectrum of fetal problems caused by maternal alcohol ingestion. Many nonspecific pathologic features have been found in the offspring of mothers who drank heavily during pregnancy. In the absence of the 3 characteristics needed to diagnose FAS, the term fetal alcohol effects (FAE) should be used. Functional disturbances have been demonstrated in some neonates who show no morphologic anomalies. Infants born to women who drank heavily throughout pregnancy showed a disturbance of 24-hour sleep–wake regulation: They slept less and had more frequent interruptions in quiet sleep episodes.[7] Naturalistic observation and electroencephalographic polygraphic studies of 2-hour sleep sessions demonstrated similar disturbances.[8,9] These may be signs of alcohol withdrawal as well as functional disturbances that can persist for many months.

Effects on Offspring

At the Boston City Hospital (BCH), women were interviewed when they registered for prenatal care between May 1974 and September 1979. Information obtained included the volume and variability of alcohol intake, use of other drugs, cigarette smoking, 24-hour dietary recall, and demographic data. Heavy drinking was defined as reported consumption of 5 or 6 drinks on some occasions, and at least 45 drinks per month.* Rare drinkers consumed alcohol less than once a month or not at all and never had 5 drinks on any occasion. Women whose pattern fell between these extremes were all classified as moderate. Throughout the 5 years of the survey more than 1700 women were interviewed; approximately 10% reported heavy drinking, 40% moderate drinking, and 50% rare drinking or complete abstention. These frequencies remained constant despite considerable attention in the media to alcohol as a pregnancy risk factor.

The first cohort of 322 offspring was examined by a pediatric neurologist who was not aware of drinking patterns or other obstetric information.[10] Neonates born to the heavy drinkers, as compared with those born to the moderate or rare drinkers, demonstrated 2 to 3 times more congenital anomalies, growth retardation below the 10th percentile, and jitteriness. None of these infants was diagnosed as having the complete FAS when examined in the newborn nursery. However, at follow-up examination, 2 children demonstrated signs in all 3 categories.

Women who reported heavy use of alcohol were informed that excessive drinking might be harmful to the unborn child.[11] Counseling sessions were scheduled to coincide with routine prenatal appointments. The content of these sessions was determined by the particular problems of the patient, ranging from reinforcement of advice given by obstetric staff to help with difficult life situations. A positive supportive relationship was sustained, and the benefits of reduction of alcohol use were emphasized. Direct criticism was avoided because it often increases guilt and interferes with efforts to abstain.

Among 39 women counseled 3 or more times, 25 (56%) were able to abstain or significantly moderate consumption before the third trimester.[12] The 25 infants born to the women who reported drinking heavily early in pregnancy but were able to moderate or abstain before the third trimester were compared with 44 infants of women who continued heavy drinking throughout pregnancy. Reduction of alcohol consumption was associated with more normal growth as measured by weight, length, and head circumference (Figures 2 and 3). Among these 69 neonates, improvement in growth was consistently associated with the mother's third trimester drinking pattern as considered independently of heavy smoking, age, parity, and trimester of registration.

These data are consistent with retrospective obser-

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* A "drink" was defined as the volume of beverage containing 15 ml (0.5 oz) of absolute alcohol, eg, 360 ml (12 oz) of beer, 48 ml (4 oz) of wine, or 36 ml (1.2 oz) of 80-proof liquor.

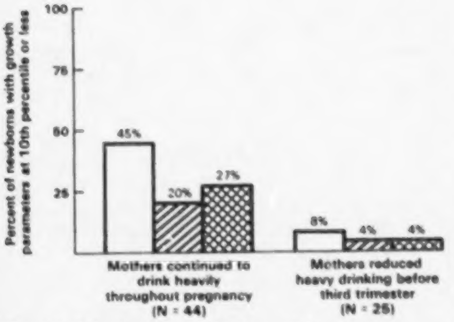

Figure 2. Reduction of heavy drinking with benefits to the newborn. Growth parameters: offspring born to women who reported heavy drinking at registration ($N = 69$). Open bar = weight at tenth percentile or less; slashed bar = length at tenth percentile or less; crossed bar = head circumference at tenth percentile or less.

vations from Germany on 29 pregnancies of alcoholic women.[9] Twenty-one (72%) of the women reduced alcohol consumption, citing concern for their child and loss of tolerance for alcohol as their reasons for limiting intake. The incidence of abnormalities among infants born to women who moderated consumption was markedly lower.

Hanson et al[13] interviewed 1529 mothers who were receiving prenatal care at a prepaid medical cooperative or at the University of Washington Hospital and clinics. In this group, 82 women reported consuming a daily average of 1 ounce of absolute alcohol or intoxication with 5 or more drinks on some occasions. A pediatrician, trained in dysmorphology and unaware of maternal drinking patterns, examined 163 infants born to heavy drinkers and controls randomly selected from the study population. Infants were categorized on the basis of features suggesting a prenatal effect of alcohol. Two infants demonstrated signs of FAS: both mothers had been clinically diagnosed as chronic alcoholics. Of the other 9 infants showing possible FAS, 7 were born to mothers who had reported drinking an average of more than 1 ounce of absolute alcohol a day during pregnancy.

Kaminski et al[14] reviewed information from more than 9000 pregnancies and reported that women who consumed more than 40 ml (1.5 oz) of absolute alcohol have a higher risk of stillbirth. Offspring born to heavier drinkers had lower average birth weights. Among heavy drinkers, placental weights also were reduced.

Sokol et al[15] studied data on 12,000 pregnancies at a single hospital and examined the relative risk of heavy drinking to offspring. They reported increased obstetric complications among the 204 women who were clinically identified as alcohol abusers. In the antepartum period, they were twice as likely to require the special care clinic and to be admitted for inpatient care. When they entered labor, the heavy drinkers had increased risk of infection, premature placental separation, tetanic uterine contraction, precipitous delivery, and meconium staining. In the alcohol abusing group, infant birth weights were lower by an average of 190 g. A significant increase in congenital anomalies was also identified. No differences were found in placental pathology.

Women who drink heavily are different from other women in a number of ways that might adversely affect outcome, including cigarette smoking, age, parity, and trimester of registration.[12,14,15] Analysis of the effects of these variables revealed that alcohol had an important causative role and that its effects were independent of the effects of the other risk factors, including cigarettes.[12,14] Sokol reported that alcohol and nicotine together compounded the risk for adverse outcome: for cigarette smoking, the risk was 1.8; for alcohol abuse, 2.4; and for cigarette smoking and alcohol abuse together, 3.9.[15]

Prevention of Adverse Effects

To design programs for prevention, obstetricians need an understanding of the probable etiologic mechanisms of the FAS and of the psychologic and environmental forces affecting the heavy drinker. Alcohol has the biochemical potential to cause a wider range of effects on the fetus than any other commonly used drug. It crosses the placenta freely, attaining the same con-

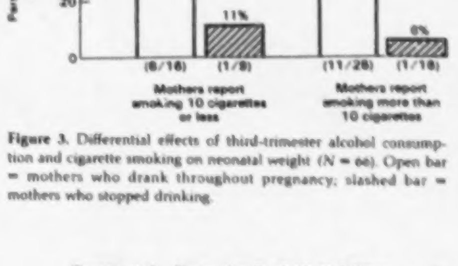

Figure 3. Differential effects of third-trimester alcohol consumption and cigarette smoking on neonatal weight ($N = 66$). Open bar = mothers who drank throughout pregnancy; slashed bar = mothers who stopped drinking.

centration in the fetus as in the mother. Many of the pathophysiologic effects that have been observed in adult alcoholics can occur in the fetus.

One theory of FAS etiology is that alcohol functions as a teratogen analogous to thalidomide. Exposure of the embryo or fetus at a critical stage can result in malformation. According to this theory, total abstinence is the only safe strategy. Once a toxic dose of the drug has been ingested during a vulnerable developmental period, the only option remaining for prevention of FAS is termination of the pregnancy.[16]

An alternative theory considers the multiple effects of alcohol on biochemistry and physiology, as well as the implications for the maternal–placental–fetal system of the entire spectrum of the pathophysiology of alcoholism. Alcohol can be expected to have multiple effects, depending on the variability of the blood alcohol concentration during various stages of pregnancy as well as on changes in the biologic susceptibility of the maternal–placental–fetal system. This conceptualization is based on an extensive review of the experimental literature, which includes models of the FAS in mice, rats, beagle dogs, miniature swine, and primates.[17] Observations of the effects of alcohol at specific stages of pregnancy must come from animal experiments. In clinical research, few drinking histories have the precision needed to clarify effects of exposure limited to 1 stage of fetal development. During the first trimester, alcohol may alter cell membranes and the embryonic organization of tissue. Throughout gestation, direct effects of alcohol on the metabolism of carbohydrates, lipids, and proteins probably retard cell growth and division. Alcohol also interferes with active transport of amino acids across the placenta, reducing the availability of essential nutrients to the fetus.[18] Vulnerability of particular organ systems may be greatest at the time of their most rapid cell division: At critical stages, this may be the cardiovascular, the urogenital, the musculoskeletal, or the central nervous system. The third trimester is the time of most rapid brain growth and of essential neurophysiologic organization for the regulation of state. High blood alcohol concentrations during this period may impair central nervous system growth and future intellectual and behavioral development.

Early damage may not be reversible; however, whenever heavy drinking ceases, an opportunity is created for catch-up growth and physiologic restitution. The primary goal of therapy is abstinence or reduction of maternal alcohol consumption. Modification of other risk factors, such as smoking and low weight gain associated with malnutrition, will reduce hazards due to synergistic mechanisms.

The obstetrician's office and the prenatal clinic are potential sites for FAS prevention programs. Health professionals who work with pregnant women should become aware of the risks of heavy maternal alcohol use and adopt new attitudes toward women who drink. Traditional pessimism about the treatment of alcoholics is not justified in the counseling of heavily drinking pregnant women. Pregnancy is a time when most women establish sustained relationships with health professionals and become more concerned about their own bodies and the well-being of their unborn children. Strong feelings of responsibility for the welfare of the unborn child motivate them to deal with problem drinking.

The 10-Question Drinking History

Problem drinkers cannot be identified by appearance or by socioeconomic characteristics. A systematic drinking history is essential and should be obtained from all patients during the initial history. In the BCH survey of prenatal clinic patients, an extensive drinking history standardized by Cahalan et al [19] was used. Because this method requires more time than is practical for clinical use, a 10-question drinking history (TQDH) was developed and incorporated into the BCH prenatal clinic record. It is administered routinely as part of the initial examination. Separate inquiry is made about the frequency, quantity, and variability of consumption of beer, wine, and liquor. The first 9 questions ascertain present drinking patterns, and the tenth explores changes in drinking habits during the past year (Figure 4).*

Use of the TQDH was demonstrated in a lecture during the orientation program for house staff at the beginning of the training year. Drinking categories were explained, with particular emphasis on the definition of heavy drinking. To increase awareness of alcohol and its related problems and to improve motivation to inquire about alcohol use, we also presented material on the biochemistry and pharmacology of alcohol and its adverse effects on the fetus. The role of the physician's attitudes in eliciting information about the use and abuse of alcohol and other drugs was discussed. Supportive counseling techniques were reviewed and the importance of the physician's positive expectations was stressed. The availability of the research treatment team for consultation with the staff was made known. Information about resources in the

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* While separate inquiry was made about the ingestion of beer, wine, and liquor, their use was combined for scoring and classifying drinking patterns. Reports on weekly consumption were converted to monthly rates for scoring purposes. Women were then classified as heavy, moderate, or rare drinkers on the basis described earlier.

Beer: How many times per week ______
How many cans each time ______
Ever drink more? ______

Wine: How many times per week ______
How many glasses each time ______
Ever drink more? ______

Liquor: How many times per week ______
How many drinks each time ______
Ever drink more? ______

Has your drinking changed during the past year?

Figure 4. Ten-question drinking history (TQDH) for prenatal use.

community for referral of patients with extensive problems was also provided.

Between September 1978 and March 1979, 186 women who were interviewed by the research program returned for their initial clinic appointment. The clinic staff administered the TQDH to 171 (92%) of these patients. Of the 171 women, 10 (6%) had reported heavy drinking to the research interviewer. Eight of these 10 women also reported heavy drinking to the clinic staff. One woman who had denied heavy drinking to the research interviewer reported it to the clinic staff. There is some discrepancy between responses, although it is not large. Most of the discrepancy is in the shift from reporting moderate drinking to the research interviewer to reporting rare drinking to the obstetrician. Reports of heavy drinking are remarkably consistent (Table 1).

Many physicians are reluctant to inquire about alcohol use. Before the inception of this project, few charts contained information on patients' drinking habits. Clinic staff systematically inquired about alcohol consumption after the inclusion of TQDH in the chart and the brief training program described above.

One explanation physicians give for failing to inquire about alcohol use is, "I wouldn't know what to do if I found problems." They feel that they lack both the knowledge and the time for problem drinkers, whom they perceive as difficult. This attitude may be overcome when obstetricians learn, through experience, that patients appreciate professional concern and often respond rapidly when brief supportive therapy is integrated with prenatal care. Physicians may also be more willing to ask when they know how to refer problem patients to community resources for treatment.

Another reason physicians give for not asking about alcohol use is "patients don't tell the truth anyway." Although the problem of denial exists in attempting to determine individual drinking patterns, when the TQDH is utilized in a direct, nonjudgmental fashion, pregnant patients seem to respond honestly to the doctor's concern. Embarrassment or defensiveness on the part of the physician is communicated to the patient and may contribute to underreporting. As it is unlikely that pregnant women would exaggerate drinking habits, a report of heavy drinking is an accurate indicator that the woman is at risk for adverse pregnancy outcome.

Integration of Counseling with Prenatal Care

When heavy drinking is identified, counseling should be initiated. Careful evaluation of the total personality is necessary in planning a therapeutic program for pregnancy, delivery, and the newborn period. Ego strength of the pregnant woman must be assessed in terms of her style of coping with anxiety and depression, her capacity to sustain relationships with family and friends, and her resourcefulness in times of adversity. Most professionals have sufficient skills to provide supportive counseling focused on the reduction of alcohol use and to provide practical help for dealing with difficult life situations.

An estimate of the risks of heavy drinking within the limitations of current knowledge should be presented to the patient. The possibility of reducing risks by abstaining for the remainder of the pregnancy should be presented positively. Decisions about continuation or termination of the pregnancy depend on the balance between the woman's capacity to abstain from alcohol and her wish to become a parent as well as on her philosophic and religious attitudes. No simple formula is available. In each case, the physician and the parents must assess risks and benefits in personal terms.

Pregnant women who drink a pint to a quart of li-

Table 1. Comparisons of Drinking Histories Reported to Research Interviewer and Obstetric Staff at Boston City Hospital Prenatal Clinic

Reported to research interviewer	Reported to obstetric staff			
	Rare drinkers	Moderate drinkers	Heavy drinkers	Total
Rare drinkers	93	5	1	99
Moderate drinkers	21	41	0	62
Heavy drinkers	0	2	8	10
Total	114	48	9	171

Z = 11.17 as measured by Kappa,[20] the observed proportion of agreement $P < .001$.

quor daily have developed a physiologic tolerance. To minimize withdrawal symptoms, the quantity of alcohol consumed should be reduced gradually over several days. At BCH, most women drinking this much were able to withdraw as outpatients, but a few were admitted to the obstetric service. Because of potential risk to the fetus, whenever possible, the use of chlordiazepoxide and other benzodiazepines and anticonvulsants was avoided during withdrawal.

Disulfiram (Antabuse) also has been suspected as a possible teratogen. In a prospective cohort of 5 pregnancies in which the woman took between 250 and 500 mg of disulfiram daily, there was 1 spontaneous abortion in the second month, 2 infants with club feet, and 2 normal babies.[21] Another teratogen surveillance program of 1320 histories identified only 2 exposed infants.[22] Both mothers had been on a maintenance regimen of disulfiram during the first trimester of pregnancy. Neither mother was known to have been exposed to alcohol or any other established teratogen during this trimester. Both infants had severe limb reduction anomalies. One infant had multiple anomalies, including radial aplasia, vertebral fusion, and tracheoesophageal fistula (Vacterl syndrome); the other had phocomelia of the lower extremities.

In our experience, alcoholic women with sufficient motivation for disulfiram therapy have all been able to modify their alcohol use without it. They have been strongly motivated by their concern for the health of the unborn child and respond promptly to counseling alone. Pregnant women who do not modify their heavy drinking within 2 weeks should be referred to specialized treatment programs.

The importance of developing special programs for pregnant alcoholic women is demonstrated by the differences in neonatal outcome between infants born to women who were able to reduce consumption and those born to women who continued heavy drinking. A pregnant woman who cannot reduce drinking after she has been informed that it will help her have a healthier child is severely addicted to alcohol. Her offspring are at highest risk for FAS. Obstetricians should collaborate with psychiatrists and alcoholism counselors to adapt existing resources for the special needs of these patients. New programs including residential treatment, day-care centers, and women's support groups also should be developed.

While the dangers of heavy drinking during pregnancy have been established, more research is needed to evaluate the effects of moderate or light alcohol consumption. The most conservative advice is to abstain from all alcohol from the time of conception through delivery and lactation. However, at this time, the danger from light drinking (less than 1 ounce of absolute alcohol per day) has not been demonstrated and should not be overstated. Exaggeration could decrease credibility of public health warnings about the adverse effects of heavy drinking. In addition, exaggeration may cause parents of abnormal children to feel guilt that small amounts of alcoholic beverages caused abnormalities which may actually be due to other factors.

Reduction of alcohol consumption during pregnancy will improve a woman's chances of having a healthier baby. This knowledge, together with the interest and concern of obstetricians, can be a powerful force for motivating her to abstain from alcohol or to reduce consumption significantly for the duration of the pregnancy. One can anticipate significant benefits for mother and infant.

References

1. Warner R, Rosett HL: The effects of drinking on offspring: An historical survey of the American and British literature. J Stud Alcohol 36:1395, 1975
2. Lemoine P, Haronsseau H, Borteryu J-P, et al: Les enfants de parents alcooliques: Anomalies observées à propos de 127 cas. Ouest Med 25:476, 1968
3. Jones KL, Smith DW: Recognition of the fetal alcohol syndrome in early infancy. Lancet 2:999, 1973
4. Clarren SK, Smith DW: The fetal alcohol syndrome. N Engl J Med 298:1063, 1978
5. Rosett HL: A clinical perspective on the fetal alcohol syndrome. Alcoholism: Clin Exp Res 4:119, 1980
6. Seidenberg J, Majewski F: Zur haeufigkeit der Alkoholembryopathie in den verschiedenen Phasen der muetterlichen Alkoholkrankheit. Hamburg Suchtgefahren 24:63, 1978
7. Rosett HL, Snyder P, Sander LW, et al: Effects of maternal drinking on neonate state regulation. Dev Med Child Neurol 21:464, 1979
8. Landesman-Dwyer S, Keller LS, Streissguth AP: Naturalistic observations of newborns: Effects of maternal alcohol intake. Alcoholism: Clin Exp Res 2:171, 1978
9. Havlicek V, Childiaeva R, Chernick V: EEG frequency spectrum characteristics of sleep states in infants of alcoholic mothers. Neuropaediatrie 8:360, 1977
10. Ouellette EM, Rosett HL, Rosman NP, et al: Adverse effects on offspring of maternal alcohol abuse during pregnancy. N Engl J Med 297:528, 1977
11. Rosett HL, Ouellette EM, Weiner L, et al: Therapy of heavy drinking during pregnancy. Obstet Gynecol 51:41, 1978
12. Rosett HL, Weiner L, Zuckerman B, et al: Reduction of alcohol consumption during pregnancy with benefits to the newborn. Alcoholism: Clin Exp Res 4:178, 1980
13. Hanson JW, Streissguth AP, Smith DW: The effects of moderate alcohol consumption during pregnancy on fetal growth and morphogenesis. J Pediatr 92:457, 1978
14. Kaminski M, Rumeau-Rouquette C, Schwartz D: Consommation d'alcool chez les femmes enceintes et issue de la grossesse. Rev Epidemiol Santé Publique 24:27, 1976
15. Sokol RJ, Miller SI, Reed G: Alcohol abuse during pregnancy: An epidemiological model. Alcoholism: Clin Exp Res 4:135, 1980

16. Jones KL, Smith DW, Streissguth AP, et al: Outcome in offspring of chronic alcoholic women. Lancet 1:1076, 1974
17. Rosett HL: The effects of alcohol on the fetus and offspring, Alcohol and Drug Problems in Women. Edited by OJ Kalant. New York, Plenum, 1980, pp 595–652
18. Lin GWJ, Maddatu AP: Effect of ethanol feeding during pregnancy on maternal-fetal transfer of a-aminosobutyric acid in the rat (Abstract). Alcoholism: Clin Exp Res 4:222, 1980
19. Cahalan D, Cisin IH, Crossley HM: American Drinking Practices. New Brunswick, NJ, Rutgers Center of Alcohol Studies, 1969
20. Fleiss J: Statistical Methods for Rates and Proportions. New York, Wiley, 1973, pp 143–147
21. Tissot-Favre M, Delatour P: Psychopharmacologie et teratogenèse à propos du disulfirame: Essai expérimental. Ann Med Psychol 1:735, 1965
22. Nora AH, Nora JJ, Blu J: Limb-reduction anomalies in infants born to disulfiram-treated alcoholic mothers. Lancet 2:664, 1977

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Summary and Recommendations: NIAAA Prospective Fetal Alcohol Studies

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THIS conference was held just five years after the first Fetal Alcohol Study Group Meeting in Milwaukee in 1975. Our initial enthusiasm and excitement has been sustained by the convergence of clinical, experimental and epidemiologic findings relevant to the health of infants and mothers. We have also become aware of the complexity of prospective studies of pregnancy in humans, an awareness gained through years of hard work. Now that a portion of the data from all four NIAAA-funded prospective studies is available for comparison, caveats concerning inherent problems in this data are presented to help clarify the findings and the limitations placed on their interpretation. Hopefully this also will indicate future directions for those developing research and public health policy.

THE INDEPENDENT VARIABLES

Collectively, these prospective studies represent the most systematic investigation of drinking patterns before and during pregnancy, surpassing previous work in terms of sample size and methodology. While self-reporting methods had been applied to studies of problem drinkers and of alcohol consumption in the general population, changes in patterns of alcohol consumption and other drug use during pregnancy had been neglected. We have discovered problems in describing precise drinking patterns at various stages of gestation. First, reports of alcohol consumption obtained during pregnancy may differ from those provided retrospectively. The impact of setting and timing may be inferred from the Boston report "Among the 327 women interviewed both prenatally and in the hospital after delivery, 10.1% of the women reported heavy drinking during pregnancy at prenatal interview and 3.6% reported heavy drinking during pregnancy in the hospital interview. Heavy drinking prior to pregnancy was reported by 10.9% and 8.2% respectively in this group" [1]. The Boston experience may be relevant for further analysis of the Loma Linda data where pre-pregnancy drinking was investigated through self-administered questionnaires which were completed by 63% of the subjects at the time of the first prenatal visit and by 37% of the mothers post-delivery [3]. All of the mothers describe their alcohol use during pregnancy on questionnaires completed after delivery.

Second, there are changes in drinking practices during pregnancy. Little *et al.* observed that many women spontaneously reduced their alcohol consumption when they become pregnant, but the heaviest drinkers before pregnancy tend to be the heaviest drinkers after conception [4]. Rosett *et al.* found that some chronic alcoholic women sustain heavy drinking despite nausea and the reduction of pleasure [7]. Some women who sustained heavy drinking throughout the first trimester could be motivated to reduce consumption by counselling which focused on potential benefits for the health of their unborn child. Different degrees of reduction, ranging from moderate to total abstinence, seemed to improve the pregnancy outcome.

Third, multiple inquiries required to evaluate changes in drinking patterns may affect alcohol consumption itself or may only affect the style of reporting. In Boston, validation of behavioral change was provided by the contrasting growth pattern between offspring of women who reported that they had or had not reduced consumption [7]. Since these repeated interviews were part of a therapeutic program, the research design did not include a test of the effects of repeated inquiry on a random sample of light and moderate drinkers.

The Cleveland study is also repeatedly inquiring about drinking behavior throughout pregnancy from a sample of positive MAST responders and a matched sample of negative MAST responders [9]. Changes in the volume pattern index (VPI) from week to week are reported, with a significant reduction among the positive MAST group. It is important to determine whether the change in VPI reflects an actual change in drinking behavior or results from a change in reporting associated with repeated interviews and counseling. It also should be noted that a positive MAST response can occur on the basis of old drinking patterns even though a woman currently abstains from alcohol intake. Information from the MAST and the volume pattern index may help differentiate risks associated with the chronic use of alcohol from those due to consumption during pregnancy.

Other independent variables which represent risks to the fetus such as the use or abuse of cigarettes or other drugs also may change during the nine months of gestation. Among the women interviewed at prenatal registration and post-partum in Boston, a comparable percent reported marijuana use during pregnancy. However only half of those who reported marijuana use reported it at both interviews; some reported at registration but not post-partum while others reported post-partum but not at registration. Nutritional habits change over the course of pregnancy and there is variable utilization of prenatal vitamins and minerals. The complexity of changes in various risk areas suggests that future research should include serial assessments of a number of risk factors from the high risk group as well as the controls.

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DEPENDENT VARIABLES

The facial dysmorphology of FAS can be described qualitatively but is difficult to quantify objectively. While the length of palpebral fissures can be measured, variability may occur due to the tone of the infants facial muscles as well as the examiner's style of approaching the baby. Measurements of weight, length and head circumference can be standardized more easily. All growth parameters must be adjusted for gestational age and also are affected by genetics, nutrition, and a wide range of other factors.

In the several prospective studies only two cases of the full FAS have been reported in neonates. Both were observed by dysmorphologists in Seattle [11]. It should be noted that the mothers of the two infants diagnosed FAS were both in the heaviest drinking category, were independently described as alcoholic, and are known to have died within four years of the birth of these children. The Seattle dysmorphologists examined pairs of infants, one from the high risk experimental group and a control infant. High risk and low risk infants would have associated differences in growth which may have alerted the examiners to subtle dysmorphic characteristics. For the pediatrician, this experience is different from consecutive examination of large numbers of babies.

Some dysmorphic features of FAS become clearer with the passage of time. In the inner city setting, sustained contact is often difficult and infants frequently are lost to follow-up. Maintenance of sample size was more successful in the Seattle health maintenance organization. The Seattle report contains the demographic characteristics of the interview sample, follow-up cohort and dysmorphology sample. It is also important to determine whether various other risk factors such as smoking, caffeine intake and nutrition differed between these groups. The Boston study examined characteristics of mothers whose babies were and were not examined as well as that of babies whose mothers were and were not interviewed [1]. Subject loss following discharge from the hospital can become a greater methodologic problem since the characteristics of the mother may directly affect the research staffs' ability to sustain contact.

The other caveats cited in the Seattle report should be underscored, particularly the differentiation between statistical significance which may be partly a function of sample size and medical significance which concerns the relationships between observed differences and their long term effects on health and development. On reviewing the published multiple regression analysis of infant mental and motor development at eight months of age [10], one finds that the variables measured account for less than 6% of the total variance in infant performance; alcohol use accounts for less than 2%. Other data presented in the paper suggests that the greatest effects are associated with alcohol consumption above eight drinks a day. Adverse effects of low levels of alcohol consumption were not demonstrated.

Multiple regression analysis has the capacity to separate the effects of confounding variables. However in considering the effects of alcohol as a continuous function of average daily consumption, medical significance may be missed. Animal experiments suggest a threshold effect. When only a small percent of the population consumes more than the threshold amount, any effects on their infants can only account for a small amount of the variance. While the outcome of their offspring may not be statistically significant in terms of the variability of the whole population, it may be critical for the affected children. Therefore, in addition to multiple regression analysis, other statistical methods should be used to study events which may occur only within small samples of the total population.

As more of the data from the four prospective studies is published, a vast amount of information will become available. This must be carefully analyzed and the findings of the four studies compared to test the validity of scientific observations and to improve the design of future research. Time constraints and the cost and complexity of data analysis may limit the full utilization of this vast body of information. Failure to completely analyze methodologic issues will result in the loss of important information and also condemn future investigators to duplicate many of the less productive efforts. The public health importance warrants the investment required for a thorough and critical review.

FUTURE DIRECTIONS FOR RESEARCH

These four prospective studies contain important information, yet underscore the inherent limitations of the large epidemiologic approach in the study of the effects of alcohol during pregnancy. Future prospective studies will improve on our early experience. As a result of these pioneering efforts the social climate for research on pregnant women may be more compatible with careful objective measurement. In the early 1970s, when these projects were being designed, some human studies committees assumed an adversary role. They were concerned that obtaining a drinking history in the prenatal clinic posed a potential danger since some women might be offended and receive no prenatal care. Objective measurement of alcohol levels in the blood, breath, or urine were considered unethical since they might be used against the mother in future custody cases.

Future studies should be conducted within the context of an ongoing health care delivery system providing sustained relationships with the entire family. Women at high risk and a control group should be selected and matched for age, parity, ethnicity and socioeconomic status. There must be consideration of multiple risks to the fetus from alcohol, cigarettes, other drugs, nutrition, and caffeine. Therapy for these multiple risks should be incorporated into the research design. No therapeutic approach succeeds in altering the addictive behavior of all subjects. Successes and failures in the therapy program will provide important data on the effects of these substances on fetal growth and development.

Objective measurement of several independent variables will be facilitated by new biochemical techniques. Established measures of alcohol in the blood, breath, urine or saliva detect only recent drinking. A sweat-patch test for alcohol recently has been developed which reliably can differentiate between a group who drank no alcohol and a group consuming an average of 1.5 oz of absolute alcohol daily, either continuously or episodically [6]. Another objective, integrated time-dose measure of alcohol consumption may be provided by means of a recent identification of an apparently specific minor glycosylated hemoglobin component of erythrocite lysates [2,5]. The relationships between reported drinking patterns and objective measures of total alcohol consumption would provide validity indicators which are lacking in all current studies. Direct measurement of the effects of smoking might be approached through testing levels of carbonmonoxyhemoglobin. Nutritional assessment should be accompanied by direct measurement of levels of zinc, folate, and other nutrients from serum, tissue, and hair. Endocrine functions of both the mother and the fetus may be measured more directly through recently developed radioimmune assays. Future studies should be conducted at alcohol research centers with assured long-term commitments of personnel and funding, as well as facilities for the biochemical measurement of the independent variables. In addition, they will need committed staffs of neonatologists and developmental psychologists to longitudinally assess growth and development and attempt to differentiate congenital, genetic and environmental influences.

The most sophisticated clinical epidemiologic approach will not attain the precision of animal experiments. Different animal models provide the opportunity to investigate specific aspects of the problem [8]. Collaboration between the clinical and the experimental disciplines which has been so fruitful over the past five years must continue if we are to fully understand the interaction of alcohol and the multiple factors which affect fetal development.

FUTURE DIRECTIONS FOR HEALTH POLICY

There was agreement by an international group of investigators at the Seattle conference that the full fetal alcohol syndrome has been observed only in the offspring of chronic alcoholic women. Therefore programs for early identification and treatment of women who drink heavily during pregnancy should be developed. Obstetricians and other health care professionals who treat the pregnant woman can be trained to obtain a systematic drinking history from each new patient and counsel those women whose infants are at risk for fetal alcohol effects. A pregnant woman who cannot reduce her drinking after she has been informed that it will help her to have a healthier child is severely addicted and her offspring are at risk. Existing alcohol treatment resources should be adapted to meet the special needs of these patients. This may also require the development of new programs including residential treatment, daycare centers and women's support groups.

Mass media campaigns may increase the general level of awareness in society of the dangers of heavy drinking during pregnancy. However they have limited therapeutic effect on those women who abuse alcohol. Direct counseling from the physicians and health professionals who provide prenatal care may be a more effective strategy. Many health professionals will remain reluctant to involve themselves in this problem until they are convinced that the adverse effects associated with alcohol have medical as well as statistical significance. Careful analysis of the data from these four NIAAA supported prospective studies should provide some of these answers and also give direction to future research.

REFERENCES

1. Alpert, J. J., N. Day, E. Dooling, R. Hingson, E. Oppenheimer, H. L. Rosett, L. Weiner and B. Zuckerman. Maternal alcohol consumption and newborn assessment: Methodology of the Boston City Hospital prospective study. *Neurobehav. Toxicol. Teratol.* 3: 195–201, 1981.
2. Hoberman, H. D. Adduct formation between hemoglobin and 5-Deoxy-D-xylulose-1-phosphate. *Biochem. biophys. Res. Commun.* 90: 764–768, 1979.
3. Kuzma, J. W. and D. G. Kissinger. Patterns of alcohol and cigarette use in pregnancy. *Neurobehav. Toxicol. Teratol.* 3: 211–221, 1981.
4. Little, R. E., F. A. Schultz and W. Mandell. Drinking during pregnancy. *J. Stud. Alcohol* 37: 375–379, 1976.
5. Nitowsky, H. M. The fetal alcohol syndrome—an overview. *Teratology* 21: 59A, 1980. (Abstract).
6. Phillips, M. and M. H. McAloon. A sweat-patch test for alcohol consumption: Evaluation in continuous and episodic drinkers. *Alcoholism: Clin. exp. Res.* 4: 391–395, 1980.
7. Rosett, H. L., E. M. Ouellette, L. Weiner and E. Owens. Therapy of heavy drinking during pregnancy. *Obstet. Gynecol.* 51: 41–46, 1978.
8. Rosett, H. L. and L. Weiner. Clinical and experimental perspectives on prevention of the fetal alcohol syndrome. *Neurobehav. Toxicol.* 2: 267–270, 1980.
9. Sokol, R. J., S. I. Miller, S. Debanne, N. Golden, G. Collins, J. Kaplan and S. Martier. The Cleveland NIAAA prospective alcohol-in-pregnancy study: The first year. *Neurobehav. Toxicol. Teratol.* 3: 203–209, 1981.
10. Streissguth, A. P., H. M. Barr, D. C. Martin and C. S. Herman. Effects of maternal alcohol, nicotine, and caffeine use during pregnancy on infant mental and motor development at eight months. *Alcoholism: Clin. exp. Res.* 4: 152–164, 1980.
11. Streissguth, A. P., D. C. Martin, J. C. Martin and H. M. Barr. The Seattle longitudinal prospective study on alcohol and pregnancy. *Neurobehav. Toxicol. Teratol.* 3: 223–233, 1981.

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Behavioral Evaluation of Fetal Alcohol Education for Physicians

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Assessment of clinical behavior has been neglected in evaluating alcohol training for professionals. Inclusion of a systematic drinking history in patient charts provides a sensitive yet simple behavioral marker. At Boston City Hospital, a Ten Question Drinking History (TQDH) was incorporated into a prenatal intake procedure and used to monitor staff behavior. Utilization of the TQDH, measured for six time periods, ranged from 92% to 33%. Obstetrical staff was more likely to complete the TQDH when the alcoholism research staff was visible in the clinic and readily available for consultation and referral.

KNOWLEDGE, attitudes, and clinical behavior are three separate dimensions which should be considered in evaluating alcohol education programs for professionals. Pre-test and post-test methodology has been utilized to assess increase in knowledge and change in attitudes. The relationship between attitudes, knowledge, and clinical behavior remains unclear with expressed attitudes often differing from behavior.[1,2] Although the ultimate target of professional eduction is appropriate behavior toward alcoholic patients, few studies have evaluated this component. Evaluation of a fetal alcohol training program focused on assessment of the number of women from whom alcohol histories were obtained.

METHODS AND RESULTS

The Fetal Alcohol Education Program at Boston University School of Medicine was developed to teach obstetricians and other health professionals to identify problem drinking pregnant women. The need for this program became apparent following a prospective study which was begun in 1974 at the Boston City Hospital (BCH) Women's Clinic. Identification of heavy drinking and therapeutic intervention were integrated with routine prenatal care. Benefits to newborns were observed among offspring born to heavy drinkers who were able to reduce consumption before the third trimester (3). Obstetricians, trained to obtain drinking histories, could provide supportive counseling.

A lecture was presented annually to residents and staff in the Department of Obstetrics and Gynecology as part of the orientation sessions at the beginning of the academic year. Material included evidence of the adverse effects of alcohol on fetal development from clinical, epidemiological, and experimental reports. Attention was given to dose response at critical gestational stages as well as to associated risk factors, including malnutrition, cigarette smoking, and use of other drugs. A Ten Question Drinking History (Fig. 1) for use in the prenatal clinic was described. The role of physician attitudes in identification and treatment of problem drinkers was discussed. The 1-hr presentation, which included case material derived from our experience at BCH, was revised annually to incorporate new research.

The Ten Question Drinking History (TQDH) was printed on the clinic chart to be incorporated into the prenatal intake procedure. This was an effort to modify staff behavior by providing a structured format for inquiring about alcohol use. The TQDH proved effective in identifying women whose level of consumption placed their fetus at risk. It also provided a format to monitor clinical behavior.

The number of charts containing drinking histories was tabulated for several time periods. Before the training program began, few charts contained drinking histories. From September

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Beer: How many times per week do you drink beer?____________________

How many cans do you have at one time?____________________

Do you ever drink more?____________________

Wine: How many times per week do you drink wine?____________________

How many glasses do you have at one time?____________________

Do you ever drink more?____________________

Liquor: How many times per week do you drink liquor?____________________

How many drinks do you have at one time?____________________

Do you ever drink more?____________________

Has your drinking changed during the past year?____________________

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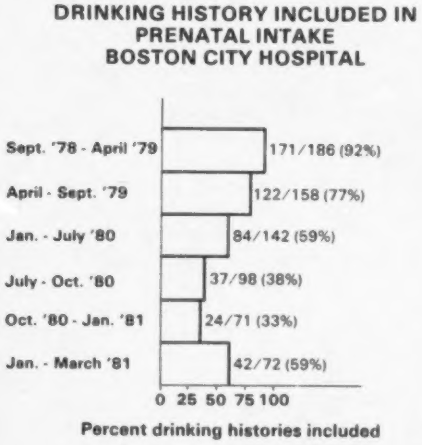
Fig 1. Ten Question Drinking History (TQDH).

Table 1. Drinking History Included in Prenatal Intake Boston City Hospital



1978 through March 1981, the percentage of patients whose drinking histories were recorded ranged from 92% to 33% (see Table 1). Many staff members participated in the intake procedure at the Women's Clinic. We were unable to monitor the clinical behavior of individual staff members.

When the training program was first presented, fetal alcohol research was being conducted in the prenatal clinic. All patients were surveyed at registration, and problem drinkers were counseled during routine prenatal visits. The research staff and the obstetrical staff frequently consulted about clinical management of patients with drinking problems. The survey at prenatal registration was discontinued in April 1979. The research staff remained available for consultation and referral; however, they no longer were present in the clinic on a regular basis. As the research staff involvement decreased, clinic staff interest in patients' drinking patterns, as measured by utilization of the TQDH, also decreased. In January 1981, the chairman of the Department of Obstetrics and Gynecology issued a directive that all prenatal charts should contain a TQDH. He also provided information about availability of research staff for consultation. Additional reinforcement may have been provided by publication in an obstetrical journal of a paper featuring the TQDH and describing benefits to the newborn following reduction of heavy maternal alcohol consumption.[3] Between January and April 1981, staff interest improved and the TQDH was completed on 59% of the charts.

DISCUSSION

Evaluation of clinical behavior is an important component of research on professional education. By simply noting the percentage of charts in which a drinking history had been recorded, we demonstrated that, throughout the study period, at least one-third of the patients were asked about alcohol use. This represented a marked increase in the number of inquiries with the inception of the training program. When support staff was highly visible, the clinic staff was more likely to inquire. A directive from the Chief of Obstetrics and Gynecology also improved compliance.

Faculty of specialty departments provide a medium for positive reinforcements and should be included in planning alcohol education programs. They should be encouraged to participate in alcoholism treatment, education, and research. Faculty members who direct clinic policies and personnel serve as role models and are crucial for success. In the absence of positive reinforcement from faculty role models, residents and students are negatively affected by faculty prejudiced against the alcoholic and ignorant about facts as described by Liepman et al.[4] Activities undertaken by research workers outside of the specialty may be limited by the relatively short duration of grant support. Since the directors of training are more apt to have sustained institutional involvement, training materials should be developed for their use.

Medical students and residents are more likely to accept information when it is presented scientifically with quantification and documentation. They recognize the complexity of issues and are skeptical when issues are presented in simplistic and moralistic terms. Medical faculty also share these values and will more readily participate in alcoholism education when the material meets scientific standards and is relevant to their patient population.

The strategy of presenting the fetal alcohol education program in the hospital setting developed after we participated in numerous daylong conferences on the fetal alcohol syndrome. These meetings were well attended by alcoholism counselors and researchers. The few physicians who attended usually were not in clinical practice. This is consistent with observations by Monahar et al.[5] that professionals who attended six 2-hr training sessions were highly motivated. Pre-tests revealed that those who came to all six sessions were less moralistic and more optimistic even before the training program than were those who attended one or two sessions. Programs in the hospital setting are more apt to reach those professionals who have little concern for the alcoholic and who avoid alcohol training sessions and symposia.

Presentations at obstetrical staff meetings at several area hospitals generated interest; however, there was no way to assess if there was a gap between interest and actual behavior. A review of literature on attitudes[6] suggests that it is considerably more likely that attitudes will be unrelated to actions than that the two are related. Bailey[7] reported changes to more positive attitudes toward alcoholics after a 30-hr course, but no increased disposition to render care.

Evaluation of alcoholism education for professionals has centered on changes in basic knowledge and attitudes. Knowledge is the easiest to describe, outline, teach, and test but cannot predict behavior. The measurement of attitudes toward the alcoholic patient and attitudinal change is far more difficult as attitudes are temporal and multidimensional and may be contradictory.[8] Measurement deals only with strength of feeling, in terms of more or less. Only those attributes which can be described in a linear continuum can be measured. Difficulties in measuring attitudes may contribute to the discrepancies observed between attitudes and behavior.

Educational strategies which force physicians to encounter alcoholics break down stereotypes.[9-11] When treatment is successful, professional optimism increases and there is increased willingness to treat additional patients. Incorporating the TQDH in the chart facilitates inclusion of a systematic drinking history as part of routine care. This increases physicians' awareness of alcohol consumption and helps destroy negative stereotypes that drinking may be a problem for others but rarely affects their own patients.

Identification of alcoholism in the early stages of the disease also increases professional optimism. Positive reinforcement occurs whenever physicians are successful in the identification and treatment of alcoholic patients. Failures and frustrations with difficult chronic alcoholic patients create negative reinforcement and discourage doctors from therapeutic involvement. Our earlier educational efforts which included exposure of medical students to alcoholics in half-way houses, detoxification centers, and emergency rooms had a paradoxical effect. The intended message was that alcoholism is an important and complex disease which physicians have the knowledge and skills to treat. The message unintentionally conveyed was that caring for the alcoholic was beyond the scope of most physicians. The alcoholic presented had reached the end-stage of the disease syndrome. The complex disruption of their health and their lives overwhelmed the medical students who developed therapeutic pessimism.

CONCLUSION

Appropriate clinical behavior toward the alcoholic patient is the ultimate objective of professional education programs. Adequate knowledge, skills, and attitudes are needed for proper therapy. However, performance on pretests and post-tests commonly used to evaluate training programs does not necessarily predict therapeutic activity. Few studies have analyzed the effect of professional training on clinical behavior.

This pilot study demonstrated that awareness of alcohol consumption in the prenatal population increased when alcohol training was included in the obstetrical department's orientation program. The TQDH provided a relatively standardized objective measurement of behavior which could be utilized to measure changes over time. Six-month and 1-year follow-up studies have been rare in evaluations of programs designed to change professional behavior. These data suggest that training must be reinforced by additional sessions which consider didactic information, professional attitudes, and clinical experiences. Information should be provided about available consultation and referral resources.

Additional aspects of clinical behavior remain unexplored. Inclusion of a summary of risk factor management in the chart would facilitate measuring follow-up procedures including counseling and referral. Differences between individual staff members in levels of compliance should be assessed. Relationships between physician attitudes and the percentage of patients reporting drinking heavily should be examined. Research efforts which provide quantitative data about behavior should improve both educational effectiveness and patient care.

REFERENCES

1. LaPierre RT: Attitudes versus actions, in Fishbein M (ed): Reading in Attitude Theory and Measurement. New York, John Wiley and Sons, 1967, pp 26–31

2. Doob LW: Behavior of attitudes, in Fishbein M (ed): Readings in Attitude Theory and Measurement. New York, John Wiley and Sons, 1967, pp 42–50

3. Rosett HL, Weiner L, Edelin KC: Strategies for prevention of fetal alcohol effects. Obstet Gynecol 57:1–7, 1981

4. Liepman M, Whitfield CL, Landeen R: Inadequate knowledge, skills and attitudes about alcoholism in medical school faculty. Alcoholism 1982 (in press)

5. Monahar V, Des Roches J, Ferneau EW: An education program in alcoholism for social workers: its impact on attitudes and treatment-oriented behavior. Br J Addict 71:225–234, 1976

6. Wicker AW: Attitudes versus actions: the relationship of verbal and overt behavioral responses to attitude objects. J Soc Issues 25:41–77, 1969

7. Bailey M: Attitudes toward alcoholism before and after a training program for social caseworkers. Q J Stud Alcohol 31:669–683, 1970

8. Thurstone LL: Measurement of social attitudes, in Fishbein M (ed): Readings in Attitude Theory and Measurement. New York, John Wiley and Sons, 1967, pp 14–25

9. Chappel JN, Schnoll SH: Doctors attitudes: effect on the treatment of chemically dependent patients. J Am Med Assoc 239:2318–2319, 1977

10. Sterne M, Pittman D: The concept of motivation: a source of institutional and professional blockage in the treatment of alcoholism. Q J Stud Alcohol 26:41–57, 1965

11. Mogar RE, Helm ST, Snedeker MR, Snedeker MH, Wilson WM: Staff attitudes toward the alcoholic patient. Arch Gen Psychiatry 21:448–454, 1969

Senator HUMPHREY. Thank you, doctor. I did not mean to preclude your statement. I was not aware that you had one or I would have asked you to present it before we went to questions.

Well, let us get back to one of the central issues with respect to your interests. I do not doubt what you say, that in the case of problem drinkers, information is not going to have much effect. But problem drinking, I would think, is not characteristic of the vast bulk of pregnant women in this country. Most of them are occasional or so-called social drinkers, and most of them, I think, from my observation, are unaware that drinking—for instance, the simple fact that alcohol passes through the placenta; I will bet that 90 percent of women of childbearing age in this country do not know that; likewise, about the effect on lactation.

The proponents of a warning label, I think, are not trying to address exclusively the problem of excessive drinking, but drinking across the entire spectrum by pregnant women or those who anticipate becoming pregnant.

So, again, I return the question of if your organization is willing voluntarily and at its own expense to engage in public information activities, what is the difference between that and putting a simple warning on an alcoholic beverage container?

Dr. ROSETT. Are you addressing me?

Senator HUMPHREY. Whoever wishes to answer.

Dr. ROSETT. I believe that Dr. Sergio Fabro's statement about the threshold model is probably closer to the evidence that has been produced from experimental evidence in animals. There does seem to be a threshold dose, and below that dose there now is evidence of no effect—either an effect in terms of growth, malformations or behavior.

As Dr. Salisbury suggested, there are entire nations where routine consumption of moderate amounts of alcohol has been practiced for many generations. One of the difficulties that doctors have in accepting this warning campaign is they do not believe it. They know that their wives and many of their patients have been drinking moderately and they have had normal babies.

Exaggeration of the danger of small amounts of alcohol confuses the issue. There is very clear-cut evidence of the danger of heavy drinking. I have seen fetal alcohol syndrome babies, as have many others. All the fetal alcohol syndrome children reported around the world have been born to mothers who were chronic alcoholic women.

At Boston City Hospital, we found that 9 percent of the women were drinking heavily when they registered for prenatal care. A similar percentage has been found at Case Western Reserve by Dr. Sokol. I believe that, in different groups, somewhere between 3 and 9 percent of the pregnant women may drink heavily.

If one takes 3 percent, of 3 million pregnancies, one is talking about 100,000 women drinking within a range where their children are at risk. They can be reached by the doctor, the nurse, or the midwife being actively involved in identifying heavy drinking and providing counseling, integrated with the prenatal care. These women do not identify themselves as chronic alcoholics; they do not go to alcoholism programs. They may be referred to programs by the obstetrician if they do not respond promptly to the supportive counseling provided by the doctor.

I believe that some of the data on the adverse effects of moderate drinking such as spontaneous abortions with one or two drinks are really an under-reporting effect, because those events occur only in the top 3 percent of the population. The heavy drinking 3 percent of the population represents a significant target group for medical intervention and they can be worked with successfully.

Senator HUMPHREY. Maybe I am missing the point here somehow.

Mr. DAVIS. Mr. Chairman, may I go back to your point again?

Senator HUMPHREY. Yes. What is the difference between paying for a public service announcement that warns of the effect and putting the message on the beverage container?

First of all, what are these public service announcements you have on this subject?

Mr. DAVIS. We have posters, we have pamphlets, we have TV and radio spots.

Senator HUMPHREY. What is the essence of the message?

Mr. DAVIS. It is: consult your physician about all aspects of your drinking and pregnancy—nutrition, drinking, and so forth. And then, of course, we have done a great deal of work through the education commission of the States and the schools in reaching teenagers. We have done a great deal of work through Dr. Mendelson's work in alerting the health care professionals

So, what we are trying to do is complete a circle. We are trying to alert the people that they should get into the medical stream, and some of these posters are directed at minority groups of women to get into the medical stream and to be guided by it.

Let me make my final point. One of our concerns is that it would be very difficult to have an accurate warning label. To get back again to your question, I want to be a little more specific about it. The American Council on Science and Health reviewed the scientific evidence available and found that there was no justification for advising pregnant women on total abstinence. That was reported in the U.S. Journal of Drug and Alcohol Dependence, a very prestigious journal in the field, with an accompanying editorial saying that, you know, this loses its credibility when you present warnings without scientific evidence to back them up.

Senator HUMPHREY. If you are willing to put out that message on your announcements, why not on the bottle? You do not think there is enough room on the bottle for all of the caveats, is that the problem?

Mr. GAVAGHAN. Well, I think I would like to advance two out of many reasons. One is that a label, we believe, would be widely misunderstood by those who would propagandize the media and the public that through adoption of such a measure, the U.S. Government is condemning any and all drinking. And I think that a labeling on any issue or subject would promptly be misconstrued by interests who believe in what is known as control of availability both here and abroad. They believe in what is called the Schmidt-de Lint theory, which is that the way to reduce alcohol problems is to apply restrictions on the industry, and labeling has long been on their agenda as one of the issues.

Eventually, if not sooner, we predict that the adoption of one label would not be enough and that there would have to be eventually a book on every bottle. And this still would not satisfy these people because they have a longer agenda which relates to availability and restrictions.

We believe that this is a health, education, treatment, and intervention problem, and that this is the approach to take. It is fundamentally sound and we support such approaches, and we believe that the discussion today should be based on research and education rather than one narrow segment of a total approach.

We feel that those who argue in favor of a label will not be satisfied with one. You would have to have a label every day of the year, and this in turn will never substitute for medical education and sound health education in our country.

Senator **Humphrey**. Well, I can understand your concern about going too far. That is always a problem, and often the reality.

Has your organization considered offering a proposed label that it would find acceptable, or are you just ruling it out entirely irrespective of whatever the language might be?

Mr. **Davis**. Well, I do not think, Mr. Chairman, that we have seen one that we feel–that is one of the problems. The health problems in this field are so complex, and this point was made, again, in the HHS-Treasury study. It is almost impossible to convey accurate, meaningful information to the consumer on a warning label because, again, it would almost take a booklet attached to the neck or something, if you went into all the ramifications.

Senator **Humphrey**. Yes. Would you object to a label that said, for instance, "Scientific research indicates that alcohol passes through the placenta into the bloodstream of the unborn," and leaves the implications of that to the consumer?

Mr. **Davis**. Well, Dr. Rosett is probably in a better position to answer it. But given the fact that there is some alcohol or some other substance related to it that goes through the placenta, I do not think that there is any evidence that that is harmful to the fetus at certain levels.

Senator **Humphrey**. Yes. That is why I am saying leaving the implications of that to be determined by the consumer, just stating that there is a research finding. Would you object to that?

Mr. **Davis**. Well, it certainly would give the impression that any consumption of alcohol during pregnancy was inappropriate.

Dr. **Salisbury**. Senator?

Senator **Humphrey**. I have not forgotten you, Dr. Salisbury. Go ahead.

Dr. **Salisbury**. I was just going to say that although I am sitting with this group and respect them very much, the March of Dimes is not necessarily in league with them on the warning label business. I think we would say that our expectations of a warning label on alcoholic beverages would neither decrease the consumption of alcohol nor decrease the incidence of fetal alcohol syndrome.

I pull out a package of cigarettes from my pocket 20 times a day and am never cognizant that that warning is on it. I pay no attention to it.

Senator **Humphrey**. Well, of course, we are not exclusively talking about the full-blown syndrome, but less serious effects. What we are searching for here is a way of getting out the message.

Does anyone disbelieve what we have heard this morning?

Mr. **Davis**. Well, Mr. Chairman, let me say that we think we are getting the message out. We have not mentioned it specifically here, but in our new phase two program we certainly are not forgetting about fetal alcohol syndrome, even though we are expanding into alcoholism and drunk driving.

We have just entered into an agreement with the Department of Health and Human Services where we are going to sponsor a poster and information card in their "Healthy Mothers—Healthy Babies" campaign that will be distributed to about 15,000 public health clinics, and it will be done in Spanish in a certain percentage as well as English.

We feel that this is the meaningful way to approach the problem, and not, again, in a rather simplistic thing of trying to come up with wording that means something on a label.

Senator **Humphrey**. Well, it is not an either/or proposal. I think we are looking for a whole spectrum of ways to disseminate information.

Dr. Salisbury, what other organizations like yours are engaged in preventing the effects of fetal alcohol syndrome? Are there any other organizations like the March of Dimes involved?

Dr. **Salisbury**. I am not aware of any except us that are engaged in the whole problem of maternal and infant health. I think there are small groups of parents of fetal alcohol syndrome babies, and so forth, around the country. But I do not know of any major, national organizations.

Senator **Humphrey**. How long has the March of Dimes been involved in this program?

Dr. **Salisbury**. We have been funding some of the research for about 10 years and have very actively had a public health education program for 6 or 7 years.

Senator **Humphrey**. What progress do you feel you have made in raising public awareness in 6 or 7 years?

Dr. **Salisbury**. I think it is quite good in public awareness. I am not sure we have been able to change behavior to any extent. Of course, we cannot measure that very well. But through our youth seminars which are held in all our chapters across the country and through our activities, as I say, with posters and pamphlets being distributed, I think the awareness is considerably greater than it was 6 or 7 years ago.

Senator **Humphrey**. Have you measured that scientifically?

Dr. **Salisbury**. No, we really have not. We get more inquiries about it from people who think they may have a problem. But, also, we get more from the general public, such as school-aged children: "Send us more information about this."

I cannot give you a baseline on points of change. I think more people know about it, but I am not sure more people are doing something about it.

Mr. **Davis**. Mr. Chairman.

Senator **Humphrey**. Yes?

Mr. **Davis**. I want to make one point clear, if I could. Our activities are conducted through organizations that are experts in the field. For example, we cooperate with the American Council on Alcoholism, and we have, for example, paid for and had distributed through their chapters these booklets on drinking and pregnancy; one is in Spanish and one is in English.

We have worked, as I mentioned before, with the Education Commission of the States and, through the State education officials, we had this booklet prepared, "What Students Should Know About Drinking and Pregnancy," which is issued widely through the secondary school systems of the States.

We are not experts, obviously, certainly not in alcohol-related problems. So, we work through the Government agencies and the private organizations that have the necessary expertise and outreach, so these people are certainly involved in this field.

What is the other one?

Mr. **Gavaghan**. The Alcohol and Drug Problems Association. We have a major project with them focusing on the working woman—a special information project for their needs.

Senator **Humphrey**. Well, I commend you for your efforts. As I said earlier, I am aware that your organization is in the forefront and certainly has set a good example. In pressing you on the labeling issue, I did not mean to obscure that or take away from that.

Likewise, I commend the March of Dimes, Dr. Salisbury, for the work that you are doing.

It is 2 p.m. and we have run out of time, and I think I have run out of questions in any case. Thank you all.

Mr. **Davis**. Thank you.

Senator **Humphrey**. The record will remain open for 15 days for the submission of further testimony.

[Material supplied for the record follows:]

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September 16, 1982

Sen. Gordon Humphrey
Senate Subcommittee on Alcoholism
and Drug Abuse
Room 6205
Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Humphrey:

Thank you for holding new hearings on "The Effects of Alcohol Consumption During Pregnancy."

While researching the 1982 revised edition of my 1977 book Just So It's Healthy - Drinking and Drugs Can Harm Your Unborn Baby, I was amazed to find that over 700 medical and scientific articles on fetal alcohol syndrome (FAS) and fetal alcohol effects (FAE) had been published by mid-1981. These are listed in "Alcohol and Pregnancy", a September 1981 bibliography compiled by Ann P. Streissguth, Ph.D., and Nancy L. Sutherland, M.L.S., of the Alcoholism and Drug Abuse Institute, University of Washington, Seattle.

No other teratogenic drug has sparked so many papers in such a short time. Why? Because although alcohol apparently causes more damage than any other teratogenic drug, there is resistance in some quarters to recognizing these dangers at moderate levels of drinking.

Ten years have passed since the original reports of FAS by Kenneth L. Jones, M.D. and David W. Smith, M.D. Ten years after the thalidomide tragedy was announced, no sane pregnant woman would ingest any amount of that tranquilizer--nor would a responsible physician sanction even moderate use of it.

Why, then, the controversy about how much alcohol is safe during pregnancy?

1. Profit motive?

How much would the liquor industry lose in sales if no pregnant woman drank alcohol? In Just So It's Healthy (p. 77-79) I estimated a low of .001 percent (1/10 of 1%) of the total annual alcoholic beverage market, to a high of .0057 percent (6/10 of 1%) of that market.

Thus, pregnant women apparently drink less alcohol in one year than the total U.S. drinking population consumes in two days.

How meaningful would this amount be to the liquor industry? Meaningful enough to advocate moderate drinking during pregnancy?

2. *Mothers' Views*

Advocates of moderate drinking during pregnancy discuss "giving up" or "being deprived" of alcohol. Interestingly, most of these advocates, particularly those in the public eye, are men. Men--who have never been, and will never be, pregnant themselves.

Women in the public eye rarely advocate moderate drinking during pregnancy. Most of us are mothers. We *know* that special, personal joy of carrying a developing human being in our bodies. We want the best for our babies. We eat the recommended carrots and cheese; we exercise and rest; we play good music and create beautiful daydreams. We avoid thalidomide and aspirin and tetracycline and anything else that we know could be dangerous for our unborn babies, who are literally part of us until they are born.

Would a sane, responsible mother slip a martini into a newborn baby's bottle? Surely not! Now back up a week, to when the mother is still carrying that child. How would she feel about drinking that martini while she's still pregnant? The effect on her unborn child would be the same as slipping the drink into her newborn's bottle. Neither the newborn nor the unborn can say "No thanks, Mom, I'd rather not have a drink." But *Mom* can! That is, she can *if* she knows the risks.

Let's help pregnant women learn *all* the risks, including those from moderate drinking. If placing a warning label on every alcoholic beverage container would help even *some* babies to be born free of alcohol-related birth defects, these labels would prove their worth to humanity.

Let us be the generation that cares enough about future generations to shout the message loud and clear: a baby cannot be born with FAS or FAE if a pregnant woman drinks no alcohol.

Sincerely yours,

Lucy Barry Robe

Lucy Barry Robe

Enclosures: excerpts from "Just So It's Healthy" pp. 25-6;27-9;77-9.
Alcoholism Magazine article 9/82

"Just So It's Healthy" by Lucy Barry Robe
CompCare Publications, 1982
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Alcohol Sales to Pregnant Women

If all pregnant women in the United States abstained from alcohol (distilled spirits, wine and beer) what would be the effect on sales?

Since 3,600,000 babies were born in the U.S. in 1981, according to the Daily News *1982 World Almanac,* this means that our country has about 3,600,000 pregnant women.

Heavy Drinkers

About 4% of all U.S. women drink "heavily" (2 or more drinks a day) according to the *NIAAA 1981 Report.* Although some decrease or quit drinking during pregnancy, let's leave this group at 4% — or 144,000 pregnant women — anyway, to show the maximum limits of how much alcohol pregnant women may be drinking.

If each "heavy" drinker has 2 drinks per day through pregnancy, these 144,000 pregnant women would consume 77,760,000 drinks per year. (2 drinks apiece for 270 days = 540 drinks x 144,000 women = 77,760,000.)

If each "heavy" drinker has 4 drinks per day through pregnancy, these 144,000 pregnant women would consume 155,520,000 drinks per year.

If each "heavy" drinker has 6 drinks per day through pregnancy, these 144,000 pregnant women would consume 233,280,000 drinks per year.

If each "heavy" drinker has 10 drinks per day through pregnancy, these 144,000 pregnant women would consume 388,800,000 drinks per year.

Moderate Drinkers

About 18% of U.S. women are "moderate" drinkers (average one-half to 2 drinks per day) according to the *NIAAA 1981 Report*. Again figuring that none cut down, this could mean 648,000 pregnant women.

If each "moderate" drinker has one-half drink per day through pregnancy, these 648,000 pregnant women would consume 87,480,000 drinks per year (one-half drink apiece for 270 days = 135 drinks x 648,000 women = 87,480,000).

If each "moderate" drinker has 1½ drinks per day through pregnancy, these 648,000 pregnant women would consume 262,440,000 drinks per year.

Rare/Occasional Drinkers

Since 40% of all U.S. women abstain from alcohol, according to the *NIAAA 1981 Report*, this leaves 38% of all women who are "rare" or "occasional" drinkers (drinking less than those classified as "moderate"). This could mean 1,368,000 pregnant women.

If each "occasional" drinker has 1 drink per month through pregnancy, these 1,368,000 women would consume 12,312,000 drinks per year (9 drinks apiece x 1,368,000 women = 12,312,000).

If each "occasional" drinker has 1 drink per week through pregnancy, these 1,368,000 women would consume 53,352,000 drinks per year (39 weeks).

If each occasional drinker has 2 drinks per week through pregnancy, these 1,368,000 women would consume 106,704,000 drinks per year.

Total Pregnant Drinkers

Are pregnant women an important share of the alcoholic beverage industry?

As we saw, the estimated 144,000 pregnant women who drink "heavily" may consume anywhere from 78 million to 389 million drinks per year.

The estimated 648,000 pregnant women who drink "moderately" may consume anywhere from 87 million to 262 million drinks per year.

The estimated 1,368,000 pregnant women who drink "occasionally" may consume anywhere from 12 million to 107 million drinks per year.

Grand total? Anywhere from 178 million to 758 million drinks per year.

Pregnant Drinkers' Share of Market

The *NIAAA 1981 Report* stated that "in the United States apparent consumption now averages about 1 ounce of ethanol — approximately 2 drinks — each day for each person 14 years of age and older." Thus, roughly 180 million people (male and female) consume about 360 million drinks every day (distilled spirits, wine and beer) or 131.4 billion drinks per year.

If pregnant women consume my above low estimate of 178 million drinks per year, that's .001 (one-tenth of 1%) of the total annual alcoholic beverage market. If pregnant women consume my heftier estimated 758 million drinks per year, that's still only .0057 of the total annual market — or six-tenths of 1%!

Indeed, pregnant women apparently drink less alcohol in one *year* than the total drinking population in this country consumes in two *days*.

Father's Role in FAS

Two groups of people are always interested in the father's role in fetal alcohol syndrome:

1) men

2) wives of alcoholics, particularly mothers of children with FAE symptoms. Some of the latter have told me that they, themselves, drank little or nothing during pregnancy.

FAS research during the past decade has concentrated on the mother. This is because no chromosome damage has been confirmed in FAS children, although some subtle changes have recently been noted in animals. And after all, the mother's role lasts 9 months, while the father's is a "one-shot"!

However, male alcoholics *can* have problems in the reproduction department: impotency, sterility, lowered sperm count, damaged sperm. Heavy drinking in *any* man affects his sexual performance: his testosterone level falls while his LH (lutenizing hormone) level rises. This produces the confusing physical state of heightened desire with lowered performance.

An adolescent boy who drinks alcohol regularly may delay his puberty by about 2 years, according to Robert A. Anderson, Jr., Ph.D., in a November, 1981, *Science* article. The University of Illinois researcher found comparable delay in mice.

The same 1981 *Science* article also reported Dr. David Van Thiel of the University of Pittsburgh showing that "drinking a pint or more of hard liquor per day for 5-8 years can produce impotency, sterility, and feminization in men."

However, "nearly all effects observed by Van Thiel and others are reversible if drinking is moderate or if heavy drinking is stopped before the damage becomes severe," according to *Science*.

"If you do a little drinking and stop," said Van Thiel, "you'll

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Non-Alcoholic Drinking during Pregnancy

If a woman's alcoholic drinking during pregnancy can cause so many serious problems in her children, what happens when a non-alcoholic pregnant woman drinks?

The culture of the U.S. revolves around drinking. Americans drink to celebrate, socialize, sleep, enhance eating, palliate pain, allay anger, lighten loneliness. Two-thirds of all women in the U.S. drink at least occasionally, according to the NIAAA 1981 *Report*.

However, trying to find out exactly what damage alcohol can do to unborn babies at moderate levels of drinking is extremely difficult.

When scientists study the prenatal damage done by prescription drugs (such as thalidomide, DES, etc.), they can check doctor's prescriptions, pharmacy records, hospital charts, as well as question the mother. Then they carefully examine the child, often aware of the exact days during her pregnancy when the mother took the drug and how much she took. When doctors compare symptoms in all the children whose mothers took a specific drug, they can often detect the precise amount of the drug that causes problems and often at which times during pregnancy.

Pinpointing alcohol intake is far more complex. Looking back, how many women can remember *exactly* how many drinks they had in — say — the second week of the third month of a specific pregnancy? Who keeps count? Particularly women who drink liquor, wine, or beer on a regular basis?

As for predictions, no sane pregnant woman would volunteer to drink a certain amount of alcohol for a few weeks or months, just to show research scientists what damage might — or might not — have occurred to her baby!

Another puzzle is genetic predisposition: some people are prone to have stomach ulcers and some are not; some people are allergic to strawberries while others are not. By the same token, some unborn babies may be prone to FAS or alcohol-related birth defects (ARBD), while others are not.

However, animal research can help here — showing us exact results when animals are given precise amounts of alcohol at selected times of pregnancy. Almost all organic symptoms of FAS seen in humans have been seen in animals whose mothers were given alcohol during pregnancy, including FAS facial symptoms. These can offer clues to what to look for in humans.

For example, because delayed puberty had been observed in female mice whose mothers were given alcohol during pregnancy, I organized a research project (Robe, Robe & Wilson) at South Oaks Institute of Alcohol Studies to see if young women began menstruating later than normal when their mothers reported heavy drinking during pregnancy. The daughters did indeed: their menstruation started an average of one and one-half years later than girls whose mothers abstained or rarely drank during pregnancy. Although this might be explained by the stress of being raised in an alcoholic home, Walter J. Bo, Ph.D., at Bowman Gray School of Medicine, recently found puberty significantly delayed if female rats were given alcohol as babies. Thus, alcohol may somehow disturb the reproductive systems of unborn and/or young females.

Even animal behavior is affected by alcohol. For example, when pregnant rats are given alcohol, their offspring are hyperactive! Animal research can thus serve as a guide to what may take place in humans.

However, it will probably be quite a few years before we know *exactly* how much alcohol is dangerous during pregnancy . . . at which times . . . to women with what kinds of predispositions.

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Fetal Alcohol Effects (FAE) also known as Alcohol-related Birth Defects (ARBD)

"A child who has Down's syndrome either has it or not. A child with fetal alcohol syndrome has the whole syndrome, but other children may have lesser effects."

Seattle Pregnancy and Health Program
Listen Magazine, 1981

When children have symptoms of fetal alcohol syndrome — but without the full-blown FAS — these symptoms are usually called either fetal alcohol effects (FAE) or alcohol-related birth defects (ARBD).

Symptoms of FAE can be seen in children whose mothers are not necessarily alcoholic, and who may not even be considered by their group to be particularly heavy drinkers.

Up to one-third of heavy-drinking mothers have babies with some of the major or minor birth defects that are symptoms of FAS. Many are born small (length and weight). Other documented problems include lower IQ's, minimal brain dysfunction (MBD), brain malformations, hyperactivity, organic problems, newborn depression, and certain newborn actions that are not quite normal. Robert J. Sokol, M.D., of Cleveland, found that one-half of his babies of "alcohol abusing" mothers had *some* abnormality.

Newborns weighed 5½ ounces less than expected when their mothers had as few as 2 drinks a day in late pregnancy, in a study conducted by Ruth Little, Sc.D., of the University of Washington.

Women who drink heavily during pregnancy have more stillbirths (babies born dead) and miscarriages.

However, miscarriage rate may go up after only 2 drinks twice a week, according to Jennie Kline of Columbia University in a July 26, 1980, *Lancet* journal report; or after 1-2 drinks a day in the second trimester, according to S. Harlap of Jerusalem's Hebrew University. These studies were reported in the NIAAA 1981 *Report* and in a November 1981 *Science* article. Ruth Little says that miscarriage rate doubles at 2 drinks a day.

In a 1977 Boston City Hospital study, 14% of the babies whose mothers drank "moderately" during pregnancy had birth defects.

Most FAS experts now believe that FAS itself is only the tip of the iceberg. They believe that FAE/ARBD are infinitely more prevalent than FAS, and should be considered regularly as a possible explanation of many other problems.

For example, women in the U.S. have about half a million miscarriages and stillbirths every year . . . about 14% of all pregnancies. How many of these are alcohol-related?

About 250,000 babies — 8% of all newborns — are born every year with birth defects. (A birth defect is "an abnormality of structure, function or metabolism," according to the March of Dimes.) How many of these are alcohol-related?

More specifically, nearly 25,000 babies are born annually with congenital heart malformations, an FAS symptom seen in 30%-40% of FAS babies. How many of these 25,000 heart problems are alcohol-related? How many of the yearly 4,300 cleft lips/cleft palates?

"About one-third of all babies weighing under 2500 grams (5½ pounds) at birth are term infants, who for some reason have not grown according to a normal rate," according to nurses Erna Ziegel and Mecca Cranley in their book *Obstetric Nursing*. About 7% of all babies are born in the U.S. with low birthweight. How many of these babies' low birthweights are alcohol-related, when we consider that only 2 drinks a day can significantly lower a baby's birth weight?

An estimated 3%-10% of school age children are hyperactive — a characteristic of FAS children. How much of this hyperactivity is alcohol-related?

How about the learning disabilities seen in about 15% of school children?

If a child is diagnosed as having FAS, doctors sometimes find FAE/ARBD in older brothers and sisters. Generally, the full FAS appears in younger family members — perhaps because the mother drinks more alcohol as her alcoholism progresses, perhaps because something about her metabolism changes as her disease progresses. Interestingly, K. K. Christoffel, M.D., reported in a 1975 *Pediatrics* study full-blown FAS in one newborn and ARBD in his fraternal twin. Two babies exposed to the same amount of alcohol before they were born — yet probably for some genetic reason, one twin was more severely damaged than the other.

Heavy Drinking during Pregnancy

Heather

When the doctor told Heather, 24, that she was pregnant, she drove her Mercedes-Benz to the country club and announced the good news to her luncheon companions over daiquiris in the club lounge.

The three women ordered a bottle of rosé wine with their vichyssoise and lobster salads. Then they discussed baby care: mainly how to find a good baby nurse, as this was to be Heather's first child.

That afternoon, Heather played tennis and had a beer afterwards.

When her husband arrived home from work, he made his usual silver shaker of martinis. Heather had 2 of these, and 2 glasses of wine with dinner.

Heather and Harry made it a rule not to drink after dinner on week nights. Even so, by the end of the first day that Heather knew she was pregnant, she had consumed 3 cocktails, 3 glasses of wine, and 1 beer — 7 drinks, or the equivalent of 10 ounces of hard liquor.

Since all of Heather's good friends in her posh suburb drank the way she did, Heather did not consider herself to be a particularly heavy drinker. Husband Harry, a corporate attorney, grew up in this community. He always had a few drinks before lunch with clients, and cocktails and wine every night, so he saw nothing out of line about his wife's drinking, either.

It so happens that Heather was not an alcoholic. However, her drinking *was* placing her unborn baby in danger.

DRINKING DURING PREGNANCY:

What happens when the experts disagree on an important issue affecting pregnant women? Confusion and frustration.

Straight Talk or Double-Talk

Double-Talk

By Lucy Barry Robe

"I'm elated—like a kid who's found the brass ring," declared Joe Takamine, M.D., chairman of the American Medical Association panel on alcoholism.

There were many similarly exhuberant reactions to recent news that the 220,000-member American Medical Association had officially adopted a policy of recommending that pregnant women abstain from drinking alcohol. Dr. Takamine and his panel—LeClair Bissell, M.D.; Stanley E. Gitlow, M.D.; David H. Knott, M.D.; Kenneth D. Miller, M.D.; and Robert A. Moore, M.D.—had worked for about eight months to formulate recommendations for the AMA leadership to act on. The process was slowed down considerably by dogged resistance from obstetricians and psychiatrists who opposed the policy.

By now, almost everyone agrees that birth defects can result from heavy drinking during pregnancy. Known as the Fetal Alcohol Syndrome (FAS), these birth defects include mental retardation, growth deficiency, learning behavioral difficulties, organic problems, and subtle but distinct facial characteristics.

But not everyone agrees about the effects of moderate drinking during pregnancy. These are known as alcohol-related birth defects or fetal alcohol effects (FAE). Ruth E. Little, Sc.D., director of the University of Washington Alcohol and Drug Institute, has identified one major common fetal alcohol effect: lowered birth weight. But because alcohol is in such wide general use, researchers feel much more time is needed for the precise measurement of all the prenatal effects of moderate drinking. Some scientists and physicians maintain that without this proof they will not accept the claim that moderate drinking poses risks for the unborn.

Thus, despite mounting scientific evidence that moderate drinking *can* cause prenatal problems, drinking during pregnancy is a hot issue both in and out of the alcohol field. The controversy is reflected in FAS public information campaigns. And because policies differ, pregnant women across the U.S. are receiving mixed messages from the media, from health agencies, and from their physicians.

The National Institute of Alcohol Abuse and Alcoholism's 1982 selective, annotated resource guide on fetal alcohol effects tries to clarify the mixed messages:

1. The abstinence or abstinence-oriented message: "If pregnant, don't drink;" or, "Since no safe level of drinking during pregnancy has been determined, the safest course of action is not to drink."
2. The limit-setting message: "If pregnant, don't drink more than one (or two) drinks per day."
3. The caution-oriented message: "Check with your doctor;" or "Think before you drink."

Abstinence-Oriented Messages

In June, the AMA joined a growing collection of medical societies and health agencies that recommend *abstinence* from alcohol during pregnancy. These include the U.S. Surgeon General's office (which had elated abstinence advocates with a similar announcement in July, 1981); the NIAAA;

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National Council on Alcoholism; Research Society on Alcoholism; a dozen fetal alcohol state task forces; the Seattle Pregnancy and Health Program; the University of Washington Alcohol and Drug Abuse Institute; Johnson Institute; American Council on Alcohol Problems, Hazelden; Christopher D. Smithers Foundation; Will Rogers Institute; Haight-Ashbury Free Medical Clinic; Rose Kennedy Center Genetic Counseling; CASPAR; and many more.

LeClair Bissell, M.D., president of AMSA and a member of the AMA panel on alcoholism, discussed the thinking behind this policy in the 1982 edition of *Just So It's Healthy* (CompCare Publications): "Whenever there's the slightest question that a drug may damage an unborn child, doctors avoid it whenever possible. To do otherwise, unless the drug were needed for the treatment of a serious illness, would be totally irresponsible, morally wrong, and legally foolhardy. Alcohol is a drug, and exactly the same rules should apply." Dr. Bissell adds, "Alcohol would never pass FDA's screening process if it were submitted for approval now. Perhaps the problem is that we've regarded it as a beverage or foodstuff for so long we've forgotten it is a drug."

Limit-Setting Messages

In 1977, when the NIAAA announced the existence of Fetal Alcohol Syndrome to the public, the announcement included an official "caution" recommending that pregnant women limit their drinking to two drinks per day. This was based on the fact that a risk had been established at six drinks per day; a risk had not been established for lower levels of alcohol intake.

Partly as a consequence of NIAAA's 1977 "caution," a few state FAS task forces and other health agencies adopted a limit-setting recommendation in the late 1970s.

In 1979, the NIAAA switched to an abstinence-oriented message, and embarked on an abstinence-oriented public information campaign. But because many of its limit-setting materials are still in stock across the country, the public gets a mixed message.

Caution-Oriented Messages

The Beverage Alcohol Information Council (BAIC), a group of ten liquor industry organizations formed to educate the public in lieu of placing warning labels on alcohol products, adopted caution-oriented messages. BAIC materials do not give direct advice about drinking, but mention the adverse effects of "excessive" and "abusive" drinking, and suggest that pregnant women consult their physicians. Henry L. Rosett of Boston University, a physician who works with BAIC on medical education, characterizes the caution-oriented stance in a 1981 paper in *Obstetrics and Gynecology*:

"At this time, the danger from light drinking (less than one ounce of absolute alcohol [about two drinks] per day) has not been demonstrated and should not be overstated. Exaggeration could decrease credibility of public health warnings about the adverse effects of heavy drinking. In addition, the exaggeration may cause parents of abnormal children to feel guilt that small amounts of alcoholic beverages caused abnormalities which may actually be due to other factors."

The March of Dimes also adopted a caution-oriented message in 1979 after previously advocating abstinence in its materials. The American College of Obstetrics and Gynecology has maintained a caution-oriented stance since 1977.

Clearing the Air

All of the alcohol/pregnancy organizations, whether scientific or for public education, appear to base drinking advice on the same premise: that scientific research has not yet determined *precisely* how much alcohol does what kind of fetal damage at which times during pregnancy.

However, this premise has been used in one way by the abstinence advocates and in a contradictory way by the limit-setting and caution-oriented groups.

The limit-setting and caution-oriented groups say that, since we cannot *prove* moderate drinking harms an unborn baby, it is unfair to ask a pregnant woman to "give up" alcohol. They further believe that pregnant mothers might suffer "harmful" fear, and new mothers "unnecessary" guilt, from supposed fetal alcohol effects which could well be due to a cause other than alcohol.

The abstinence advocates, on the other hand, say that *because* we do not know a safe limit, the safest course is to abstain, at least until such time as we ever *do* discover a limit.

Abstinence advocates also point out that mothering begins *before birth*; that all unnecessary risks should be avoided; and that, if a pregnant woman has difficulty giving up alcohol for an unborn baby's sake, she may have a drinking problem.

Would a sane, responsible mother slip a martini into a newborn baby's bottle? Surely not, you say. Right. Now, back up a week to a time where the mother is still carrying the child. How would this same woman feel about drinking that martini while she's still pregnant?

The effect on her unborn child would be the same . . . that is, the same as slipping a martini into the child's bottle.

Neither the newborn nor the unborn can say, "No thanks, Mom, I'd rather not have a drink." But Mom can. That is, she can *if* she knows the risks.

Lucy Barry Robe is a New York writer. The revised second edition of her book on alcohol and pregnancy, Just So It's Healthy, *is published by CompCare Publications.*

Senator **Humphrey**. The subcommittee stands adjourned.

[Whereupon, at 2 p.m., the subcommittee was adjourned.]

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